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Occupational Safety and Health Administration

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OCCUPATIONAL EXPOSURE TO BENZENE

Occupational Safety and Health Standards

[4510-26]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Benzene

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Permanent standard for the regulation of benzene.

SUMMARY: This standard is based on a determination by the Occupational Safety and Health Administration (OSHA) that the available scientific evidence establishes that employee exposure to benzene presents a cancer hazard—specifically, the hazard of developing leukemia. Therefore, in accordance with OSHA's regulatory approach to the control of employee exposure to carcinogens, this standard limits employee exposure to benzene to the lowest feasible level, in this case 1 part benzene per million parts of air (1 ppm) as an 8 hour time—weighted average concentration, with a ceiling level of 5 ppm for any 15 minute period during the 8 hour day. The standard also prescribes limits on eye and skin contact with benzene.

The standard provides for the measurement of employee exposure, engineering controls, work practices, personal protective clothing and equipment, signs and labels, employee training, medical surveillance and recordkeeping.

EFFECTIVE DATE: March 13, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue NW., Room N3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: This permanent Occupational Safety and Health standard is issued pursuant to sections 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911. The new standard on occupational exposure to benzene which appears at 29 CFR 1910.1028, applies to all employment in all industries covered by the Act. For reasons set out below, the standard does not apply to the distribution or use of gasoline and other fuels, used as fuels, subsequent to discharge from bulk terminals. Moreover, the standard applies labelling and training requirements only to sealed, intact containers of benzene.

This document also amends Table z-2 of 29 CFR 1910.1000 by adding a footnote which provides that benzene exposures not covered by the new § 1910.1028 are still covered by the exposure level and other requirements of § 1910.1000. Pursuant to section 4(b)(2) of the Act, OSHA has determined that this standard is more effective than corresponding standards now applicable to the maritime and construction industries and currently contained in Subpart B of Part 1910, and Parts 1915, 1916, 1917, 1918 and 1926 of Title 29, Code of Federal Regulations. Therefore, those corresponding standards are superseded by the new standards in § 1910.1028. A new paragraph (c) is added to § 1910.19 to clarify the applicability of this new benzene standard to the construction and maritime industries.

I. Background

Benzene (C_6H_6) is a clear, colorless, non-corrosive, highly flammable liquid with a strong, rather pleasant odor. Benzene's low boiling point and high vapor pressure cause it to evaporate rapidly under ordinary atmospheric conditions, giving off vapors nearly three times heavier than air.

Benzene is produced primarily by the petrochemical and petroleum refining industries by a process called catalytic reformation, which converts certain lower octane hydrocarbons into higher octane aromatics. These two industries are responsible for 94 percent of the total U.S. production of benzene. Recovery through catalytic reformation, including the benzene formed from the hydroalkylation of toluene, accounts for almost 80 percent of the total quantity produced. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, was once the major source of benzene. Today, however, it accounts for only 6 percent of the total U.S. production.

The production of benzene is rapidly expanding with approximately 11 billion pounds produced in 1976. Only eleven other chemicals and only one other hydrocarbon (ethylene) are produced in greater tonnage in the U.S. Approximately 86 percent of this benzene is used chiefly as an intermediate in the production of other organic chemicals, including styrene, phenol, and cyclohexane. The remaining amount is used primarily in the manufacture of detergents, pesticides, solvents and paint removers. Benzene is also present as a component of motor fuels, averaging less than 2 percent in gasoline.

The first major industrial use of benzene, however, was as a solvent in the rubber industry just preceding World War I. During World War I, benzene production was stimulated greatly by the demand for and resulting production of toluene in the manufacture of explosives. The large quantities of benzene which were produced, resulted in its more widespread use as a starting point for the manufacture of various organic compounds. This situation led to greatly increased uses of benzene as a solvent in the artificial leather, rubber goods, and rotogravure industries.

Industries and processes currently using benzene include the chemical, printing, lithograph, rubber cements, rubber fabricating, paint, varnish, stain removers, adhesives, and petroleum industries. Benzene is also used extensively in chemical laboratories as a solvent and as a reactant in numerous chemical applications. Where benzene is produced and used in large amounts, it is generally used in enclosed systems, although exposures can occur during liquid transfer operations, from equipment leakage and carryover losses, and in maintenance operations.

II. History of Regulation

Benzene has been recognized as a toxic substance capable of causing acute or chronic effects since 1900. In 1927, on the basis of extensive examination of exposed workmen and animal inhalation data, Winslow recommended an exposure limit of 100 ppm for benzene (Ex. 156-3, Annex D).[1] In 1934, partially as a result of the fact that benzene toxicity in the shoe leather industries was a serious problem in that state, the Massachusetts Department of Labor and Industries established a Division of Occupational Hygiene (Ex. 156-3, p. 2). Relying on reports by Bowditch, Hunter, Mallory and Elkins of cases of benzene poisoning occurring at concentrations below 100 ppm, the Massachusetts Division of Occupational Hygiene reduced the maximum acceptable limit (MAC) to 75 ppm (Ex. 156-3, p. 6-7). In the 1940's, as a result of blood abnormalities and one death among leather workers exposed to benzene concentrations ranging from 40 to 80 ppm, Massachusetts lowered the permissable limit of benzene exposure to 35 ppm (Elkins Ex. p. 7).

The American Conference of Governmental Industrial Hygienists

[1] The exhibit numbers used in this document refer to the certified exhibit list of the benzene rulemaking proceeding. The first number designates the particular exhibit on that list. Where the exhibit contains more than one item, the second number references the particular item of the exhibit. The designation "PC" refers to posthearing comments in Exhibit 217. The designation "Tr" refers to the transcript of the benzene hearing and indicates the pages of that transcript which are referenced.

All references in this document are intended to provide examples of record support for the information stated.

(ACGIH) recommended in 1946 a threshold limit value (TLV) for benzene exposure of 100 ppm. This TLV was reduced in 1947 to 50 ppm. In 1948, following Massachusetts' lead, ACGIH adopted a TLV of 35 ppm. In 1963, a TLV of 25 ppm was proposed by the ACGIH. The effects of benzene noted by ACGIH at this time were blood changes, aplastic anemia and other blood dyscrasias. No mention was made of any association of leukemia with benzene exposure (Ex. 191). It was not until 1974 that the ACGIH adopted the TLV of 10 ppm which had sometime earlier been recommended by the American National Standards Institute (Ex. 156-3, p. 7).

The present OSHA standard for benzene (29 CFR Part 1910.1000, Table Z-2) was adopted in 1971 from the Z 37.4—1969 consensus standard of the American National Standards Institute (ANSI). The OSHA standard was adopted without rulemaking under the authority of section 6(a) of the Act. It prescribes, as the ANSI standard, an 8-hour TWA of 10 ppm with an acceptable ceiling concentration of 25 ppm and, in addition, allows excursions above the ceiling to a maximum peak concentration not to exceed 50 ppm for more than 10 minutes in any 8-hour work period. Neither the ANSI standard nor the resultant OSHA standard was based on the possible leukemogenic effects of exposure to benzene.

In 1974, pursuant to section 22(d) of the Act, the Director of NIOSH submitted to the Secretary of Labor a criteria document concerning occupational exposure to benzene which stated that "the possibility that benzene can induce leukemia cannot be dismissed." (Ex. 32A, p. 1). However, NIOSH recommended retention of the existing permissible exposure limit of 10 ppm and ceiling concentration of 25 ppm as measured over a 10 minute period. This recommendation was not based on benzene's potential leukemia hazard.

In a letter to the Secretary of Labor, dated April 23, 1976, the United Rubber, Cork, Linoleum, and Plastic Workers of America urged that an emergency temporary standard regulating occuptional exposure to benzene be issued (Ex. 2-42). This request was denied on May 18, 1976 by then Secretary of Labor, William J. Usery (Ex. 2-43).

Also in 1976, the National Academy of Sciences, under contract with the United States Environmental Protection Agency, reviewed the literature concerning health effects of benzene exposure (Ex. 2-4). The Academy concluded that benzene must be considered a suspect leukemogen.

In August 1976, NIOSH submitted to OSHA an updated criteria document which revised its earlier assessment of 1974 (Ex. 2-6). On the basis of a review of old studies and new data, NIOSH concluded in that document that benzene was a leukemogen. This report further pointed out that "it is apparent from the literature that benzene leukemia continues to be reported." NIOSH, therefore, recommended that since no safe level for benzene exposure could be established that, "no worker be exposed to benzene in excess of 1 ppm in air." Following publication of the updated criteria document, the Director of NIOSH recommended to the Assistant Secretary of Labor, by letter dated October 27, 1976, that OSHA publish an emergency temporary standard for benzene establishing the exposure level at 1 ppm (Ex. 2-6).

Based on the information supplied by NIOSH, OSHA issued on January 14, 1977, voluntary "Guidelines for Control of Occupational Exposure to Benzene," recommending that exposure to benzene in air not exceed an 8-hour time-weighted average to 1 ppm in any 8-hour shift of a 40 hour week (Ex. 2-44).

In January 1977, NIOSH informed OSHA that workplace environments had been found in St. Mary's and Akron, Ohio where a sufficient number of employees had been exposed to benzene for a number of years to facilitate an epidemiological study of health risks (Ex. 2-45). The worksite was a manufacturing plant owned by Goodyear Tire and Rubber Company which utilized benzene at various stages in the production of pliofilm. The preliminary conclusions of the epidemiological study, which NIOSH conducted of the pliofilm workers, were transmitted to OSHA on April 15, 1977. In his letter of April 15, 1977, transmitting this report, the Director of NIOSH again urged that an emergency standard be issued (Ex. 2-7).

On May 3, 1977, the Assistant Secretary for OSHA issued an Emergecy Temporary Standard for Occupational Exposure to Benzene (42 FR 22516), pursuant to sections 6(c) and 8(c) of the Act, Secretary of Labor's Order No. 8-76, and 29 CFR Part 1911. A correction document was published on May 10, 1977 (41 FR 23601), and an amendment to the emergency temporary standard was published on May 24, 1977 (42 CFR 26429). The evidence and findings supporting issuance of the emergency temporary standard and its amendment and a discussion of its provisions are set forth in the aforementioned FEDERAL REGISTER publications. The emergency temporary standard was to have been effective on May 21, 1977. However, as a result of challenges to that standard, filed both in the Court of Appeals for the District of Columbia (*Industrial Union, AFL-CIO* v. *Bingham*, No. 77-1395) and in the Court of Appeals for the Fifth Circuit (*API* v. *OSHA*, No. 77-1516), a temporary restraining order was issued by the Fifth Circuit on May 20, 1977, and the standard never officially went into effect.

On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452). The emergency temporary standard and its preamble, which the new proposal supplemented, were incorporated in that proposal. The FEDERAL REGISTER document setting forth the proposal also contained a notice of hearing scheduling an informal public hearing to be held pursuant to section 6(b)(3) of the Act, and requesting the submission of written comments, data, views and arguments on all the issues raised by the proposed permanent standard and the emergency temporary standard. Subsequently, on June 24, 1977 (42 FR 32263), OSHA excluded from the scope of the benzene hearing and from the final permanent standard those activities related to the storage, transportation, distribution, dispensing and sale of gasoline as a fuel subsquent to its discharge from bulk terminals. OSHA explained in that notice its intention to assess the regulatory action to be taken to protect workers involved in these activities after conclusion of the deliberations of a joint EPA-NIOSH-OSHA Task Force.

The public hearings on the benzene proposal were held July 19 through August 10, 1977. A total of 95 individuals appeared at these hearings as witnesses. Among the witnesses were employers and employer associations from a variety of industries: petroleum refining, petrochemical, oil and gas production, aviation fueling; and coke ovens and coke by-products. In addition, representatives of the affected workforce, including a number of employees who have been exposed to benzene, unions, government agencies, public interest groups and other interested parties appeared. Furthermore, comments were received from representatives of other industries, such as analytical and research laboratories, paint manufacturing, construction, maritime, and rubber manufacturing and from users of pure benzene as well as users of benzene contaminated solvents. Public participation was representative of a large segment of the benzene users. The verbatim transcript of the hearings, as well as the numerous comments, exhibits and briefs submitted to OSHA before, during and after the hearings, are part of this rulemaking record, along with other relevant documents. The hearing record was originally scheduled to close on August 20, 1977 but, at the request of industry participants, the record was kept open until September 2, 1977 for the submission of addition-

al evidence and until September 27, 1977 for the submission of briefs, summaries and arguments.

In conjunction with the development of the proposed standard, OSHA prepared a draft environmental impact statement. The draft environmental statement was published in the FEDERAL REGISTER (42 FR 27455). On June 17, 1977, the Council on Environmental Quality published a notice of availability of the benzene draft environmental impact statement (Ex 7). In addition to the 45 day comment period specified in 29 CFR 1999.4(g), the environmental impact of the proposed standard was also an issue for the benzene hearing as provided by 29 CFR 1999.4(h) and the notice of proposed rulemaking (42 FR 27452). A notice of availability of the final environmental impact statement for benzene was published on February 3, 1978 by EPA (43 FR 4674).

In addition to the draft environmental impact statement, OSHA prepared an economic and inflationary impact assessment of the proposed standard evaluating factors relevant under section 6(b) of the Act (29 U.S.C. 655 (b)(5), Secretary of Labor's Order 15-75 (40 FR 54484) and Executive Orders Nos. 11821 (39 FR 41501) and 11949 (42 FR 1017). The notice of the proposed standard indicated that the economic impact of this proposal was to be considered at the hearing (42 FR 27452) and certified that the economic and inflationary impact of the proposed standard has been carefully evaluated in accordance with Executive Orders 11821 and 11949.

This permanent benzene standard is based on a careful consideration of the entire record in this proceeding, including materials relied on in the emergency temporary standard, materials referenced in the proposal, and the record of the informal rulemaking hearing including the transcript, exhibits and pre-hearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-059, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue NW., Washington, D.C. 20210.

III. PERTINENT LEGAL AUTHORITY

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards.

Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring the existence of safe and healthful workplaces. The act provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. (Section 6(b)(5).)

Sections 2(b) (5) and (6), (20), (21), (22), and (24) of the Act reflect Congress' recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose-response data may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be based on the best available evidence. The legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d Session, p. 18 (1970). This Congressional judgment is supported by the courts which have reviewed standards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "it remains the duty of the Secretary to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient." "Society of the Plastics Industry Inc. v. Occupational Safety and Health Administration," 509 F. 2d 1301 (C.A. 2 1975). cert. den. 95 S. Ct. 1998, 4 L. Ed. 2d 482 (1975). A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standard for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

> Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision-making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.

"Industrial Union Department, *AFL-CIO* v. *Hodgson*," 499 F. 2d 467, 474 (C.A.D.C. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare, S. Rep. No. 91-1282, 91st Cong., 2d Sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. *"Society of the Plastic Industry, Inc.* v. *Occupational Safety and Health Administration,"* supra at 1309.

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examination (section 6(b)(7)). Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)). The permanent standard for benzene was developed on the basis of the above legal considerations.

IV. HEALTH EFFECTS

A. GENERAL

Inhalation is the primary route of entry of benzene in man. Benezene diffuses rapidly through the lungs and is quickly absorbed into the blood. The rate of absorption is greatest during the first five minutes and thereafter declines significantly. Benzene saturation of the circulating blood may reach as high as 70-80 percent saturation level within the first 30 minutes. However, relatively complete saturation of the blood may not be attained for two to three days.

The benzene absorbed by the circulating blood is distributed throughout the body where, because of its liposolubility, it tends to accumulate in various body organs in proportion to their fat content.

Upon removal from benzene exposure, the concentration of benzene in the expired breath follows an exponential decay curve, reflecting removal of benzene from various body compartments. Elimination via this route for relatively high concentrations has been estimated to range from 12 to 50 percent of the total amount of benzene absorbed in humans.

Most of the absorbed benzene remaining ultimately is metabolized by enzymes contained in the liver to derivatives which are more water soluble thereby facilitating their removal by the kidneys. A first intermediate in the biotransformation of benzene is believed to be benzene epoxide, a highly reactive chemical. This is one of several candidates—others: Hydro-

quinone and catechol, (Snyder Tr. 3229) suggested as the active agent responsible for benzene's hematotoxic effects. Phenol, and to a lesser extent, hydroquinone, pyrocatechol, and phenyl-mercapturic acid are the primary metabolites of benzene found in urine.

B. ACUTE EFFECTS

Exposures to high concentrations of benzene produce an almost immediate effect upon the central nervous system. Benzene concentrations near 20,000 ppm are fatal within minutes, with death occurring from acute circulatory failure or coma, with or without convulsions. Milder exposures produce a period of nervous excitation, euphoria, headache and nausea, followed by a period of depression which can result in cardiovascular collapse and/or unconsciousness. The occurrence of nonspecific nervous disturbances as an after-effect of acute exposures is dependent on duration of unconsciousness and/or severity of circulatory failure. Breathlessness, nervous irritability, and unsteadiness in walking have been observed to persist for a period of several weeks. Inhalation of still lower concentrations (250–500 ppm) yields signs and symptoms of mild poisoning, characterized by vertigo, drowsiness, headache, and nausea. Rapid recovery from these symptoms usually occurs following cessation of exposure.

These effects due to acute exposures to high concentrations of benzene have been recognized for many years and are well documented in classic toxicological textbooks and literature.

Direct contact with the liquid may cause erythema and blistering. Prolonged or repeated skin contact, even with small quantities of benzene, has been associated with the development of a dry, scaly dermatitis, or with secondary dermal infections.

C. CHRONIC EFFECTS

1. *Background.* The primary focus of this regulation is to minimize worker risk resulting from chronic exposure to low levels of benzene. These effects of benzene exposure in man have been recognized for approximately 80 years. As benzene attacks the hematopoietic (blood-forming) systems and especially the bone marrow, its toxicity is manifested primarily by alterations in the level of the formed elements in the circulating blood (red cells, white cells, and platelets). The degree of severity ranges from mild and transient episodes to severe and fatal disorders. The mechanism by which benzene produces its toxic effects, although under investigation, is still unknown. (Goldstein, Ex. 43.B, p. 132).

The adverse hematopoietic effects of benzene, including leukemia, have been documented in a variety of industries and occupations and include the rubber, shoe, rotogravure, painting, chemical processing, can manufacturing industries and more recently, the manufacture of natural rubber cast film. These studies range from single case reports, through cross-sectional studies to retrospective studies of morbidity-mortality among a defined cohort of workers industrially exposed to benzene. An important distinction among these investigations is that the cross-sectional method detects cases of mild benzene-induced hematotoxic effects in current employees who do not demonstrate signs of overt toxicity, whereas the retrospective method detects overt and fatal toxic effects subsequent to termination of employment.

OSHA is aware of the varying quality of the individually reported studies. Based on a review of the entire set of studies, taken as a whole, the accumulated evidence is conclusive that benzene exposure is causally related to the induction of leukemia (a cancer of the blood-forming system), various cytopenias (decreased levels of a formed element in the circulating blood), aplastic anemia (a non-functioning bone marrow) and to development of chromosomal aberrations.

The evidence supportive of this conclusion is derived from: (a) A high degree of association of blood dyscrasias with benzene exposure; (b) the apparent lack of a similar association with other known volatile chemicals in the same workplace; (c) outbreaks of hematotoxicity temporarily related to the introduction of benzene to an industry and conversely, a reduction in blood-related disease when other solvents are substituted for benzene; and (d) the experimental demonstration of marrow toxicity in animals solely exposed to benzene (Goldstein, Ex. 43B, p. 133).

The following studies are representative, although by no means all inclusive, of the published literature on the chronic effects of benzene exposure. These investigations do, however, illustrate the diversity and variability of the effects which dominate published reports. There are also several recent reviews and summaries concerning the hematological effects resulting from benzene exposure (See: Vigliani and Forni, Ex. 2-15; National Research Council, Ex. 2-4; NIOSH, Ex. 2-3, 2-5; NYU report; Ex. 43.B and ORC/Jandl, P.C. 34; Snyder and Kocsis, Ex. 2.B-288, and the International Workshop on the Toxicology of Benzene ("International Workshop") (Ex. 18).

2. *Non-Malignant Blood Disorders.*

a. *Human studies.* The most common effect resulting from chronic exposure to benzene is a decrease in the levels of erythrocytes (red blood cells), leukocytes (white blood cells) and thrombocytes (platelets) in the circulating blood. In simplified terms, a decline in red cells is termed anemia, a decrease in the level of white cells is leukopenia and a decline in the platelet count is called thrombocytopenia. Persons found to have depressed blood cell counts may or may not depending, in part on the severity of the decline, display overt physical symptoms. Anemia results in a decreased capacity of the blood to transport oxygen to various parts of the body, and persons so diagnosed may appear pale and weak and fatigue easily. However, the non-specific symptoms may develop gradually and not require medical attention until there are significant declines in red cell counts and blood hemoglobins. Chronic anemia may also result in physiological adjustments by the cardiovascular system and exacerbate difficulties in those with coexisting disease such as coronary insufficiency or chronic obstructive bronchopulmonary disease (Wintrobe, Ex 2A-107, p. 532). Since white cells provide a defense against many diseases, persons with leukopenia are prone to recurrent infections. Goldstein has written that "Infections are a dreaded complication of bone marrow toxicity and not uncommonly associated with a cause of death in benzene-induced pancytopenia"[3] (Ex 43B, p. 144). Thrombocytopenia results in an impaired clotting of the blood, and persons with this disorder may exhibit bleeding tendencies, such as easy bruising, nosebleeds, and hemorrhage.

[3] In the NYU review of "A Critical Evaluation of Benzene Toxicity", Goldstein uses the term pancytopenia in a general sense, defined as a decrease in the level of circulatory erythrocytes, granulocytes, and platelets. His rationale is that there is excellent evidence which suggests that all of these cell lines originate from a common precursor stem cell (Exhibit 43B, p. 135). While noting that aplastic anemia is, in a pure sense, an absence or a decrease in identifiable granulocyte, erythrocyte, and platelet precursors within the marrow itself, Goldstein finds that it is useful to include aplastic anemia or hypoplastic anemia under the category of pancytopenia. This is because in some human cases of pancytopenia induced by benzene and in some animal experiments, a hyperplasia of the bone marrow is observed; also there exists the possibility that sampling errors may affect attempts to quantitate bone marrow precursor cells, since only a small fraction of the marrow is observed by aspiration techniques.

However, Jandl feels that aplastic anemia is not a sufficiently explicit term to describe failure of "marrow to provide an adequate population of dividing blood cells for the 3 series of formed elements," and observes that the terminology "aplastic anemia" has been applied to states of chronic or non-acute marrow suppression, whether or not anemia was the most striking feature (ORC/Jandl PC 34, p. 83, Add. 3(i)). Other terms used synonymously have been "hypoplastic anemia, bone marrow failure, refractory anemia and aregenerative anemia." Based on the degree of severity exhibited, Jandl recognizes 2 phases of marrow failure:

Footnote continued on next page.

Pancytopenia and aplastic anemia are more serious conditions in which all 3 formed elements are depressed. These non-cancerous diseases may, in and of themselves, be fatal. An additional concern is that some or all of these disorders induced by benzene, may, if allowed to continue, either progress to or represent a preleukemia stage which may eventually evolve into a frank leukemia.

Among the early studies describing benzene toxicity was that of Selling (Ex 2-12). He observed a significant depression in the levels of circulating blood cells in workers employed where benzene was used as a solvent for rubber. Because of the depressed condition seen in the marrow of his patients and the results of extensive animal experiments (where he was able to produce both destructive and "regenerative" effects by subcutaneous injection of benzene), Selling suggested that the cause of the cytopenias observed in the workers was due to an aplasia of the marrow.*

An important early milestone of the benzene literature was the 1922 report by Hamilton entitled "The Growing Menace of Benzene (Benzol) Poisioning in American Industry" (Ex 159.C).

The document attempted to alert the medical community to the dangers associated with chronic benzene poisoning which was less well known than acute toxicity. This was followed several years later by the reports of the National Safety Council (NSC) which reported the prevalence of known cases by chronic benzene poisoning. These results are summarized by Jandl as follows:

> The magnitude of toxicity—primarily consiting of lowered blood cell counts—was shockingly high. Over half of the workers exposed for a year or more had abnormalities or cytopenias of the blood cells, a great proportion had pancytopenia, and a number of deaths were noted, characterized by preceding pallor, weakness, easy bruising, hemorrhage and often fulminant infections (ORC/Jandl, PC 34, p. 10-11).

More data relating occupational exposure to benzene to the occurrence of blood disorders was provided in the late 30's and mid-40's by the studies of Greenburg et al., Mallory et al., and those of Hardy and Elkins.

Greenburg and co-workers (Ex. 2-8) investigated the problem of benzene toxicity among 332 workers employed in three rotogravure processes in New York City. In addition to physical examinations, including medical and occupational histories and laboratory tests, workplace air samples, and chemical analysis of ink solvents was performed in an attempt to provide a correlation with medical findings. Exposure data in Plant A revealed that of 11 samples taken, 8 were in excess of 100 ppm, in Plant B, 14 of 24 samples showed levels above 100 ppm and in Plant C, 6 of 13 samples exceeded 100 ppm, but of the total 48 samples taken, 33 were below 200 ppm. The medical results revealed that clinically evident degrees of "poisoning" were seen in 130 workers of which 22 had severe poisoning and 6 required hospitalization. Five of the workers with the most severe hematologic pictures expressed no subjective complaints, and physical examinations were negative. It is noteworthy that the individual sensitivity to bezene varied greatly. Moreover, the authors noted that the benzene-related blood changes may be persistent and could continue to develop even after exposure had ceased.

In the same year, Mallory et al. (Ex. 2-9) reported autopsy findings in 19 workers exposed to benzene from 6 months to 12 years, but no data from the work environment was available. The author noted that significant changes were consistently found throughout the entire hematopoietic system including the marrow, liver, spleen, and lymph nodes. Of the 19 cases studied, 6 exhibited hypoplasia of the bone marrow, whereas 9 cases showed hyperplasia and 2 were diagnosed as leukemic (1 acute myeloid; 1 acute leukemic). The authors concluded that exposure to benzene under varying conditions provided diverse reactions and that individual variation was of great importance.

In 1948, Hardy and Elkins (Ex. 2-10) investigated an artificial leather plant in Massachusetts where in 1946, a man employed as a coater for 12 years became ill and died from benzene poisoning. Sixteen of the 52 workers at the plant exhibited a "remarkable deviation" in more than one blood component, but none were clinically ill. Benzene concentrations taken in 1938 ranged from 45 to 80 ppm, and thereafter repeated tests at the work station of the deceased subject revealed a concentration of about 60 ppm. Elkins stated "[D]uring World War II, however, the plant worked long hours, so that presumably his (the decedent's) exposure overall had been greater than would be indicated by the concentration of benzene found." (Elkins, Ex 156.3, p. 7). However, on the basis of this case, Elkins and others revised the PEL in Massachusetts to 35 ppm. The authors also concluded that workers exposed to benzene should have routine complete blood examinations and stressed the importance of preemployment medical evaluations which should include a medical history and a hematologic baseline.

In 1956, Savilahti reported on 147 workers who used a rubber adhesive dissolved in benzene, and who were exposed to approximately 400 ppm benzene (Ex. 2-95). Blood tests demonstrated hematological deficiencies in 73% of those examined. Thrombocytopenia, the most common symptom, was observed in 62% of those tested, followed by anemia (35%) and leukopenia (32%). Deficiencies in all 3 cell types were observed in 21% of those examined and deficiencies in two cel—types in 14%. As a result of this investigation, the use of benzene as an adhesive solvent was discontinued.

In a nine-year follow-up to the Savilahti report, Hernberg et al. (Ex. 2A-252) reexamined 125 of these workers previously exposed to benzene who were free of such exposure since 1956. This is one of the few studies available which presents a longitudinal assessment of workers previously exposed to benzene for which follow-up exceeded 2 years. The results showed a greater tendency toward recovery of leukocytes than erythrocytes or platelets; a finding which is in agreement with other investigations. Among male workers, the mean erythrocyte levels remained depressed for 9 years and were significantly less than the values reported for the control group. Despite recovery in the mean level of the platelet counts during the nine-year interval, concentrations for both men and women remained significantly below that of a control group. Based on their findings, the authors stated that "The analysis also showed that the prognosis of the severe cases did not differ from that of the mild ones, provided the acute stage had been passed." (p. 204).

Worker exposure in the rubber coating industry to petroleum naphtha containing up to about 10% benzene was reported by Pagnotto et al. in 1961 (Ex. 159A). Several hemoglobin values less than the lower limit of normal were observed among 47 men given blood examinations. Benzene concentrations ranged from essentially zero to over 100 ppm, with a substantial number between 10 and 25 ppm. Their exposure to benzene ceased in 1965.

In 1973, blood tests were repeated on 18 of these workers who were still employed by the firm, the others having retired or left for other jobs (Pagnotto et al., Ex. 156.3.B). Selection bias may

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Footnote continued from preceding page.

"[B]y convention, a diminution in the level of all blood cells produced in the marrow accompanied by evidence that bone marrow cellularity is deficient, but from which recovery occurs, usually, termed 'pancytopenia.' And by convention, a more sustained, more severe, more likely fatal suppression of the marrow is termed 'aplastic anemia.'" (P.C. 26B, p. 83, Add. 3(1)).

OSHA recognizes the usefulness and the technical reasons for Jandl's establishment of quantitative diagnostic criteria for various non-malignant blood disorders and his "reassignment" of diagnoses contained in the literature according to this classification scheme. However, for convenience sake, the terms "pancytopenia" and "aplastic anemia" are used interchangeably throughout the preamble except when discussing particular points contained in Jandl's review. In these instances, the terminology will reflect Jandl's more definitive nomenclature.

be inherent in this report as the retirees who were excluded may have been more likely to have had blood abnormalities. The blood picture of 14 out of 18 employees was characterized as "essentially normal" (Elkins, Ex. 156.3, p. 9); of the remaining 4, one was anemic, 2 were leukopenic and 1 was both anemic and exhibited leukocytosis (an elevated white blood cell count).

In 1969 Klinche et al. reported hematological damage at relatively low benzene concentrations (Ex. 2B-304). Eighteen roofers engaged in painting operations for an average of 17 years were investigated. Based upon a careful evaluation of the available results of hematological examinations, 6 were classified as suffering from early stages of benzene intoxication, 7 were suspected of chronic benzene intoxication and the remaining 5 were classified as having a normal blood picture. The paint solvent contained 0.12 percent benzene and benzene concentrations (as determined by Drager gas detector tubes) ranged from trace amounts to 15 ppm. Concentrations of toluene and xylene vapor up to 133 ppm were also found. It was not possible to quantitate past exposure to aromatic solvents. The authors concluded, however, that:

> In the case of painted or coated areas of sufficient size, even small traces of these aromatics in the work material (benzene, toluene, and xylene) even in the open air, can cause respiratory air concentrations of the level of the MAC value (15 ppm for benzene). After the workers have been exposed for a sufficiently long time, one must assume that hematological damage will result.

In a recent survey, Aksoy et al. compared the hematological findings of 217 apparently healthy male workers who were exposed to as much as 210 ppm benzene when adhesives containing benzene were utilized (Ex. 2-11). The duration of exposure ranged from 3 months to 17 years. Hematological abnormalities were seen in 23.5% of the workers. Leukopenia, with or without thrombocytopenia, was the most common finding. In addition, relative to controls, benzene exposed workers were found to have a statistically significant reduction (p less than 0.001) in mean white cell and platelet counts. Aksoy and his colleagues reported a considerable variability in the 11 bone marrow specimens studied. The aspirates showed both hypocellularity and hypercellularity (a decrease and an increase in the number of cells present), a finding consistent with his previous reports. (See Aksoy et al. Ex. 2A-290). In 33 percent of the workers examined, the hemoglobin levels fell below the lower limit of normal. Aksoy was reluctant to ascribe the anemia to benzene exposure since it was correctable by iron therapy. However, Goldstein commenting on Aksoy's findings that "the mean corpuscular volume (MCV) was in the high normal to slightly elevated range (80-96 um^3) which is unusual for iron deficiency and more in keeping with a benzene effect." (Ex. 43B, p. 140).

In 1977, Dow reported that 2 of the 594 individuals occupationally exposed to benzene died of non-malignant blood disorders, compared to 0.2 deaths expected (DOW/OH/Ex. 154, Table 6). One worker died of pernicious anemia 4 years after retirement. His exposure was estimated to have averaged 30 ppm for approximately 184 months. The second employee, who died of aplastic anemia, had an estimated exposure of 5 ppm for approximately 98 months. Because of the small numbers involved, the significance of Dow's findings is subject to some question, but the trend of excess death is consistent with the evidence presented above.

An issue deserving discussion is the similarity and difference between benzene-induced non-malignant blood disorders and those resulting from other causes. In the NYU report, Goldstein noted that:

> While the literature is inadequate to draw firm conclusions, the progression and outcome [fatality rate] of benzene-induced pancytopenias does not appear to differ substantially from that of published series of patients with idiopathic aplastic anemia (Ex. 43.B, p. 145).[2] (Ex. 43.B, p. 148)

The NRC report comes to a similar conclusion:

> [T]he available evidence does not indicate that the reported benzene-induced blood dyscrasias differ in any way from similar dyscrasias which are caused by other myelotoxic agents or for which the etiology is unknown (NRC, Ex. 2-4 p. 4).

On the other hand, Jandl contends that the high degree of reversibility of benzene-induced non-malignant blood disorders distinguishes these disorders from those caused by other agents which are idiopathic in nature. He reports that the chance for recovery in idiopathic aplastic anemia is 16%, that for drug-related aplastic anemia it is 33% and that based upon a review of 169 patients with benzene-induced aplasia reported between the years 1939-1975, the prognosis for recovery is 87%. (ORC/Jandl, Ex. 34, p. 37) Furthermore, he notes that milder forms of blood disorders resulting from benzene exposure appears to be 100% reversible (ORC/Jandl, PC 34, p. 39).

[2] However, Goldstein does suggest three possible differences between benzene-induced pancytopenia and so-called idiopathic aplastic anemia: the first is the observance of marrow hyperplasia in benzene-induced disease; the second is the presence of lymphocytopenia; and the third is "relatively frequent but inconsistent" reports of red blood cell macrocytosis resulting from benzene exposure. (Ex. 43.B, p. 148)

OSHA is aware that literature indicates that many cases of nonmalignant blood disorders may be reversed. For example, Maugeri has stated:

> the hemopathy due to benzol can, as in most cases studied by us, be cured if it is diagnosed immediately (Maugeri & Pollini Ex. 156. I p. 2).

Hernberg et al. in a follow-up study of 125 workers stated that: "the prognosis of these patients proved to be more favorable than might have been expected." (Ex. 2A-252, p. 209). Also, both Tabershaw and Aksoy have noted the reversibility of various cytopenias (Tr. 2547).

However, certain other investigators report that these disorders have persisted for as long as 12 years after cessation of benzene exposure. Goldwater and Tewksbury noted continued blood abnormalities in 10% of 108 men examined 24 months after exposure ended. (Ex. 141). Helmer observed abnormalities in 25% of 60 patients followed for 16 months, including 2 deaths. Rejcek and Rejskova found that 8 of 4500 workers manifested persistent leukopenia 12 years after exposure. (Cf. Hernberg, Ex. 2A-252, p. 204). Aksoy observed a further distinguishing feature of severe blood disorders resulting from benzene exposure. In over 100 cases of aplastic anemia classified as idiopathic or associated with etiological agents other than benzene, no cases of leukemia were observed (Aksoy, Ex. 60, p. 6A). This contrasts to the development of leukemia among some cases of aplastic anemia associated with benzene exposure.

As is apparent from the above discussion, there is no unanimity of opinion whether benzene-induced blood disorders persists, and are reversible after cessation of benzene exposure and whether such disorders differ from those resulting from other known or unknown causes.

OSHA recognizes that in many cases these disorders appear to be reversible, within the definitions of "normality" or "reversibility" used by the individual authors. However, it is not known whether for particular workers the blood indices actually return to pre-exposed or baseline valves. Because the original literature does not provide suitable long-term longitudinal analysis including adequate sample size, preexposure values nor baseline hematological values for comparative purposes on an individual basis, it is difficult to decide how much reliance can be placed on such studies. Moreover, the evidence is insufficient to determine whether or not individuals who have "recovered" are at greater risk to subsequent development of leukemia.

Finally, OSHA is unable to verify Jandl's quantitative estimates of recovery as the sources selected for his calculations are not adequately presented to permit the development of

valid inferences. Consequently, the Agency does not believe it appropriate to conclude that these non-malignant blood disorders will in all cases, be reversed to the individual's normal values.

b. *Animal Studies.* One of the first studies describing experimentally induced benzene toxicity was published by Selling in 1916 (Ex. 2-12). He was able to produce both destructive and "regenerative" effects in rabbits by subcutaneous injections of commercially pure benzene in olive oil. Bone marrow specimens clearly demonstrated a constant, well defined aplasia associated with the disappearance of leukocytes in the peripheral blood. Later studies conducted by Gerarde demonstrated that a reversible hematopoietic injury in rats was produced at a concentration of 1 ml/kg administered by subcutaneous injection for 14 days (Ex. 2-64).

In an extensive review of experimental benzene intoxication (Ex. 43.B, Ch. V), Leong observed that the results from most of the inhalation studies reported up to Spring (1977) are difficult to interpret due to inadequacies in the experimental design. Many of the studies were conducted without proper control groups to allow comparison of hematologic values against experimental results. Factors such as age, sex, strain, hormone status and to a greater extent, emotional reactions of the animals and techniques used for blood sampling are known to affect hematological parameters. Because of these defects, many of the animal studies do not provide sufficiently definitive exposure-effect information.

In 1944, Svirbely and colleagues exposed rats to benzene vapors at a concentration of 1,000 ppm for 7 hours per day, 5 consecutive days a week for 28 weeks (Ex. 2A-201). Benzene-induced leukopenia was observed during the first half of the exposure period, followed by an increase in the white cell count during the latter part of the experiment. The significance of these results is unclear since similar shifts in the white cell count occurred in the non-exposed control group.

The hematological findings obtained in inhalation experiments at lower concentrations have demonstrated considerable variation. Guinea pigs and rats exposed to an average of 88 ppm benzene for 8 hours per day for 5 days a week demonstrated a mild leukopenia after 32 and 136 days of exposure, respectively (Cf Leong, Ex. 43.B, pp. 89-90). Deichman et al. reported in 1963, that benzene can effect hematological changes, at even lower concentrations (Ex. 2-16). Eight groups of rats were exposed to benzene vapors at average concentrations of 831, 65, 61, 47, 44, 31, 29, and 15 ppm, respectively. The duration of exposure was 5 hours per day, 4 days per week for periods ranging from 5 weeks to 7 months. Exposure to the 3 highest concentrations resulted in significant leukopenia after 2-4 weeks. A moderate, but definite leukopenia was reported in the groups exposed to 47 and 44 ppm after 5 to 8 weeks. No demonstrable alterations were observed at the 3 lowest concentrations during the 7 month experiment.

In a preliminary report submitted to OSHA prior to the rulemaking proceedings, Reinhart found no significant deviation of blood counts in test rats exposed to 388 ppm for 6 hours/day, 5 days a week for 12 consecutive weeks (Ex. 115. B.8). However, significantly depressed WBC counts were observed in mice, while in guinea pigs a progressive leukocytosis was observed which continued even into the post-exposure period. Reinhart used no control group, and the number of animals used per test group is considered to be inadequate.

Finally, Laskin and Goldstein prepared an abstract for the International Workshop on Toxicology of Benzene in Paris, November 9-11, 1976 describing their chronic benzene exposure studies (cf. Snyder, 156.2, p. 5; Ex. 178). For more than two years 150 Sprague-Dawley rats and 300 mice of 3 different strains were exposed to 100 or 300 ppm benzene 6 hours daily, 5 days per week. Anemia was observed in mice but not in rats. However, lymphocytopenia was observed in all animals without similar reduction in the granulocytes until the terminal stages of benzene poisoning. This study suggests that lymphocytopenia may be an early marker for benzene toxicity.

Based on the record, the extent of non-malignant blood disorders resulting from benzene exposure is uncertain. Based only on reports contained in the literature, Jandl has calculated a number of cases and deaths annually due to aplastic anemia in the United States. Based upon data derived from several consecutive case series over the past 15 years, Jandl estimates that a 2% "probable" and 2%" possible" benzene etiology for cases of aplastic anemia (presumably not including milder disorders such as pancytopenia). Using the annual figure of 420 cases of aplastic anemia in the United States, Jandl arrived at an approximation that "about 10 and possibly 20 patient die annually due to benzene exposure." (P.C. 26B, p. 40-1, 86-87).

Goldstein suggested several reasons why the true incidence of pancytopenia resulting from benzene exposure may be seriously underestimated (Ex. 43B, pp. 138-39):

(a) That mild cases of pancytopenia may not be discovered unless searched for since they often cause no overt symptoms.

(b) That since hematoxicity induced by benzene is a phenomenon well known to the medical community, such cases tend not to be recorded in the literature, and

(c) In cases of idiopathic aplastic anemia, possible relevant exposure to benzene may have been overlooked.

OSHA believes that the present data does not permit an accurate assessment of the morbidity or mortality for benzene-induced on nonmalignant blood disorders.

C. CONCLUSIONS

Industry participants have argued that the present permissible exposure limits (10 ppm TWA and 25 ppm ceiling) provide adequate protection against the non-malignant effects of chronic exposure to benzene. (AISI brief, PC 36, p. 51, 66; MCA brief, PC 35, p. 32).

Snyder has noted, "[i]n both animals and man the lowest level of exposure demonstrated to produced bone marrow toxicity was approximately 40 ppm." (Tr. 3224-25). Elkins believes that threshold-for injury to the blood-forming system is between 25 to 50 ppm (Tr. 3210); Tabershaw (Ex. 149A, p. 6) stated that cytopenia has not been demonstrated to occur below 25 ppm. ACGIH (Ex. 156.3D) and the International Workshop on Toxicology for Benzene, both recommended a 10 ppm TWA and 25 ppm ceiling. (Ex. 17).

Attention was drawn to the Dow morbidity study in which no abnormal blood findings were observed among 287 workers exposed to benzene for 1 to 20 years, at concentrations estimated to range from 2 to 30 ppm (Ex. 154).

The Pennzoil Company commented to OSHA that from the past nine years, 160 employees exposed to 1-5 ppm benzene have been monitored by blood test, with up to 25 years work experience for some there has been "no clinical evidence of medical problems associated with benzene". (Ex. 41.1, p. 2). However, no data were presented to allow an assessment of this statement. Others have reported similar views to OSHA again without formal presentation of data. (Joyner, Tr. 2286-87; Texaco, Ex. 41-4, p. 2, P.P.G. Industries, Ex. 6-41, p. 2 and Up John, Ex. 6-4, p. 1). It should be noted that these submissions were characterized by the American Iron and Steel Institute as largely "• • • anecdotal in nature" (Ex. 36, p. 64). In further support of its position, industry cites the 1974 NIOSH criteria document recommendation that a 10 ppm TWA as a "conservative limit" (Ex. 2-2, p. 73).

It is clear, there is no dispute that bone marrow toxicity can result from exposure to benzene above 25-40 ppm range. Furthermore, it is recognized that higher dosages produce increased response and that lower dosages are

associated with reduced response. It is not clear, what adverse health effects occur below 20 ppm.

There are suggestions of hematological alterations (other than chromosomal aberrations) at concentrations below 25 ppm. Pagnotto et al. indicated that such effects occurred among workers employed in rubber coating industy exposed to concentrations for the most part between 6 and 25 ppm benzene (Ex 2A-116; Tr. pp. 360-361). Horiguchi has reported small changes in leukocyte function concentrations as low as 10 ppm, in the absence of any marrow change and with only slight variations in leukocyte count and leukocyt phagocytic activity among workers exposed to benzene in concentrations of 0.8-6 ppm (Ex 2A-161, p. 7). And there are also other reports of less apparent effects at airborne levels of 6-16 ppm in workers who do not exhibit characteristic hematological abnormalities. (Kahn and Muzyka, Ex 2A-260). It is not possible at this time to establish with any confidence a consistent dose-response relationship between benzene exposure and adverse health effects.

Where exposure information is available, it is generally area sampling and not personal exposure data that is reported. It is difficult to determine individual worker exposure based on area sampling. Compounding this difficulty are problems related to the fluctuating character of occupational exposure; the small amount of long-term data; and the fact that in small populations, workers with heightened sensitivity may not be encountered. At lower exposure levels, there is a paucity of data to provide a basis for definitive conclusions as to the extent of nonmalignant effects. In this regard Battle states that:

> [E]ven a cursory study of the literature reveals a distressing lack of exposure-hematologic effect data particularly in the low benzene exposure area of less than 10 parts per million. (PC 26C, p. 2).

Moreover, the absence of pre-exposure hematological values for comparative purposes limits the usefulness of the few studies and reports which are available, because we cannot tell whether a particular worker studied with blood values at either extreme of the normal range is suffering adverse effects. Therefore, the available literature is insufficient to permit construction of dose-effect curve.

As indicated above, the quality of evidence available in the record is considered insufficient to permit meaningful conclusions concerning exposure to benzene at low levels and resulting health effects. Industry participants have cited the 10 ppm level established by the ACGIH as evidence that this level can be considered safe. However, in establishing TLV's, ACGIH recognizes that for some workers harmful health effects may result from exposure to the toxic substance at levels below the TLV. Therefore, the 10 ppm TLV for benzene is recognized by ACGIH as a level which does not protect all workers from material impairment of health.

Leukemia aside, with benzene we are dealing with an etiological agent well-documented to produce a variety of blood abnormalities, some of which are fatal. OSHA is aware of several studies reporting blood abnormalities at levels below 25 ppm, at levels perhaps as low as 10 ppm. Because of these considerations, and the wide range of human sensitivity to benzene, OSHA cannot determine a minimum effect level for benzene and, furthermore, cannot conclude that 10 ppm provides sufficient protection against non-neoplastic effects to all workers. OSHA recognizes that prudent public health policy, and established toxicological principles necessitates setting the permissible exposure limit sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees. It is customary to use a safety factor of 10-100 or greater depending on the seriousness of the toxic effects and the nature of the data being relied upon. That is, the lowest levels at which effects had been observed would be reduced by the safety factor chosen in establishing the exposure limit. Taking this approach in the case of benzene would lead to a permissible exposure substantially less than 10 ppm without regard to the issue of leukemia and the view that no safe level can be established for the carcinogenic risk.

IV. LEUKEMIA

A. DEFINITION AND DESCRIPTION OF THE DISEASE

Robbins defines leukemia as:

> Leukemia may best be considered as a neoplasm (cancer) of the white blood cells and is so classified in the International Lists of Causes of Death. It is characterized chiefly by: The appearance of abnormal, immature white cells in the circulating blood; diffuse and almost total replacement of the bone marrow with the leukemic cells; and widespread infiltrates of the liver, spleen, and other tissues, analogous to metastatic dissemination of solid tissue cancer. (Ex. 2-24, p. 728).

Once leukemia is diagnosed there is virtually no chance of recovery. There are different categories of leukemia, depending on the duration of the disease, I.E., acute or chronic; an increase or non-increase in the number of abnormal cells, i.e., leukemia or aleukemia; and the cell type involved, i.e., myelord, monocytic or lymphoid. Goldstein also emphasizes that, "there are other differences between various subtypes of leukemia in terms of incidence, clinical course, prognosis and presumably etiological mechanism" (Ex 43B, p. 156).

The most prevalent subtype of leukemia in adults, and the type most commonly associated with benzene is acute myelogenous leukemia (AML). This disease is variously known as acute myeloid leukemia, acute granulocytic leukemia, and acute myeloblastic leukemia (ORC/Jandl, PC 34). There are several variants of AML, probably related to the pluripotential of the precursor cell and include erythroleukemia, (DiGuglielmo's Syndrome) and acute monocytic leukemia (myelomonocytic, or monomyelocytic). (ORC/Jandl, PC 34, p. 71).

Despite advances in leukemia therapy and the fact that half the adults diagnosed with AML enter into a remission (generally averaging 6 to 8 months) the prognosis of this disease remains poor (ORC/Jandl, P.C. 34, p. 73). Those who enter into remission have life expectancies averaging from 12 to 18 months, and those who fail to respond to therapy have a 50 percent survival rate of only 3 to 6 months. Aksoy noted that in his experience, for cases of benzene-induced leukemias, the period of survival after discovery was short, usually less than 6 months (Tr-275).

Myeloproliferative disorders, including chronic myelogenous leukemia (CML) have only occasionally been attributed to benzene. Lymphocytic leukemia is also subdivided into acute and chronic subtypes. The acute form (ALL), the type commonly seen in children, has only rarely been associated with benzene exposure. Chronic lymphocytic leukemia (CLL), a slowly progressive disease, and often not a cause of death, generally occurs late in life. There have been several reports associating CLL with benzene, most particularly in several reports of French origin. The evidence as to chronic lymphocytic leukemia, which will be discussed in detail later, does not appear to be conclusive.

B. STUDIES—HUMAN

Evidence in the record clearly demonstrates that benzene is a human leukemogen. Aksoy testified that the first case of leukemia due to benzene exposure was that published by Noir and Claude in France in 1897. (Aksoy, Tr 154). In 1939, Mallory, et al. described two cases of leukemia resulting from chronic exposure to benzene which supplemented ten previously reported in 1935 by Penati and Vigliani. (Mallory, Ex. 2-9), Mallory et al. stated:

> Certainly no more favorable conditions for the development of neoplasm can be imagined than prolonged and intense stimulation of reproductive activity, and simultaneous arrest of maturation.
>
> The evidence that chronic exposure to benzene produces leucemia in human beings is still incomplete but it is accumulating at a

rate and to a volume which command serious consideration. (Ex. 2-9, p. 365).

In 1965, in a partial review of the literature, Browning tabulated 61 cases of leukemia among individuals having reported prior exposure to benzene (Ex 2-31). The majority (40) were of the myeloid series—including 12 cases of erythroleukemia, 7 were classified as lymphatic and the remaining 14 grouped under the heading of "aleukemic leukemia" (a type characterized by a decline in white blood cell number).

Vigliani and Saita, in their review of 47 individuals suffering from benzene hematoxicity between the period of 1942 and 1963, presented clinical and laboratory accounts of six additional cases, all of whom were diagnosed as having haemocytoblastic leukemia (Ex 2-27). The duration of exposure of these individuals to resins, inks, varnishes, or glues containing varying concentrations of benzene ranged up to 19 years. Data on the concentrations of benzene in the workplace environment were extremely limited or non-existent. Occupational histories and medical status prior to the final diagnoses were not available, but the authors stated that "attribution of the cases (of leukemia cited) to the exposure cannot be doubted." During the years 1962-63, Vigliani and Saita noted a sharp rise in the diagnosis of leukemia among individuals having reported prior exposure to benzene which coincided with an increase in the number of newly diagnosed benzene poisoning cases. The risk of acute leukemia for the workers exposed to benzene in Milan and Pavia was estimated to be about 20 times greater than the risk for the general adult population. (Ex. 2-27). In 1975, Vigliani and Forni observed that in the rotogravure industry no new cases of aplastic anemia nor of leukemia were found among workers exposed solely to toluene after this solvent was substituted for benzene in 1964. Although there have been some reports of hematological disorders associated with toluene exposure (See Girard et al., Ex. 2B-283), the finding of Vigliani is in concert with the conclusion of Brair that, toluene and benzene are "* * * quite different chemical entities from toxicological and pharmacological points of view" and that, "toluene free from benzene can be safely used in industry as a suitable solvent in replacement of benzene." (Ex. 39-5, p. 7). Vigliani and coworkers also observed that workers exposed to toluene did not exhibit chromosomal aberrations, a "finding" observed by these authors in employees who worked with benzene.

In 1972, Aksoy et al. reported the deaths of 4 Turkish shoemakers resulting from their exposure to benzene for periods ranging from 6 to 14 years (Ex 2-29). At the time of the study, air concentrations were found to be between 150-210 ppm of benzene. Previous occupational exposure data were not provided. Two of the four patients developed acute leukemia approximately two and three years after the occurrence of aplastic anemia, although the other two did not. These case reports are supplemented by surveys of newly diagnosed cases in a medical referral area. Aksoy summarized and updated his findings at the benzene rulemaking (Ex 60). He pointed out that from 1967 to 1973, he had observed 26 patients with acute leukemia or preleukemia[4] associated with benzene exposure. Based on a population of 28,500 shoeworkers in the area, Aksoy estimated the incidence of leukemia to be twice the prevailing value of 6/100,000 observed in the general population of Western nations. From September 1973 to 1975, 14 additional cases were admitted to the hematology departments in Istanbul and Cerrahasa Medical Schools making a total of 40 in all. Thirty-four of these patients were among the groups of shoeworkers described previously. Aksoy either examined the cases personally or reviewed the charts.

API has criticized Aksoy's use of the baseline figure of 6/100,000, citing a statement from Clemmenson, that the incidence rate for a standard European population is 8 to 14/100,000 (API Ex. pp. 50-51). However, Aksoy has testified that the two-fold excess estimate among benzene/exposed shoeworkers may be underestimated since the incidence of leukemia among the Turkish population is only 3.0 per 100,000. Moreover, Aksoy stated that "undoubtedly there were other additional patients among shoeworkers who were not included in our study" (Ex. 61, p. 2). Aksoy's findings of a decline in leukemia cases during the past several years after other solvents were substituted for benzene (Aksoy, Ex. 61, 99. pp. 2-3) further provides, in an inverse manner, additional supportive evidence for the causal relationship between benzene and leukemia. This finding reinforces the results of vigliani discussed above.

In his testimony, Marvin Sakol, an Akron hematologist, described what he considered an epidemic of a rare form of leukemia among workers employed in a small department at a local industry (Ex. 61). Over a nine year period, beginning in 1954, he observed nine cases of acute myeloblastic leukemia, including "at least four and probably all nine" with DiGuglielmo leukemia (erythroleukemia). Due to the rarity of erythroleukemia Vigliani noted that the 20 or more cases attributable to benzene, reported in the literature seem to be significant (Ex. 2-49). Diagnoses from slides in some of Sakol's cases were confirmed personally by DiGuglielmo. He learned with much difficulty that all of these cases were exposed to benzene while employed in a Pliofilm operation at a plant subsequently studied by Infante et al. Sakol testified that he had knowledge of additional cases of benzene-related leukemia which have not been included in the NIOSH study. These cases may never be recorded officially because the families refused permission to release the names of the decedents for fear of loss of compensation and job. This testimony indicates an underestimation of the leukemic risk among Pliofilm workers.

Based on the hypothesis that the risk of leukemia was higher among workers who were exposed to benzene and medical X-rays, Ishimaru et al. conducted a retrospective epidemiological investigation examining the relationship between occupation and environmental factors, other than A-bomb exposure, and the incidence of leukemia in Nagasaki and Hiroshima between 1945 and 1967 (Ex. 2-33). Fifteen occupations were selected in which there had been exposure to either medical X-rays or solvents, especially benzene and its derivatives. This case-control study compared all cases diagnosed as definite or probable leukemias between 1945 and 1967 and residing at the time of the onset of the disease, in Hiroshima or Nagasaki. Controls were matched for city, sex, date of birth (±30 months), distance from the atomic bomb explosion, and residence in either city at the onset of disease. Four hundred ninety-two leukemia cases were identified, and matched controls were obtained for 413. Three hundred and three adult cases with the onset of leukemia at age 15 years or over and their controls were compared. The risk of leukemia was found to be significantly higher (about 2.5 times greater) among those with a history of employment in occupations in which various volatile solvents were used as compared to those without. The relative risk was 1.8 times higher for chronic leukemia and 2.9 times higher for acute. Eighteen of the leukemia cases associated with solvents were located in distant and non-exposed radiation areas and were considered too far from the A-bomb explosion for radiation to have enhanced the increased risk. Accepting the source of error inherent in the method which was used to collect the data, the results of this study nonetheless reinforce the observation that an increase in leukemia existed in that portion of the population exposed to radiation and employed in an occupation where solvents especially benzene, were used.

[4] The criteria used for the diagnosis of preleukemia were similar to those of Wintrobe: "[P]releukemia seems a reasonable term * * * when this diagnosis of AML may be suspected but cannot be made with any confidence." (Ex. 2-107, p. 1477).

In 1970, Girard et al. published an epidemiological study (Ex. 2B-283) undertaken to determine previous exposure to benzene or toluene in 401 patients suffering from malignant hemopathies. Extensive interviews about their work environment and chemical analyses of solvents were utilized to estimate exposure. Their findings demonstrated that compared to a control group admitted for non-hematological diseases there was a statistically significant greater frequency of past exposures to benzene or toluene among subjects with aplastic anemia, chronic lymphocytic leukemia and acute leukemia.

In April 1977, NIOSH submitted to OSHA a preliminary report by Infante et al. of a study of leukemia among benzene-exposed workers employed in the production of natural rubber cast film (Pliofilm) (Ex. 2-57, Ex. 2A-271).

The study included all white males assigned to the Pliofilm production area who were hourly employees and who at any time between January 1, 1940 and December 31, 1949 had direct exposure to benzene at the Goodyear Akron and St. Mary's plants. Only the men employed in a section having known potential exposure to benzene ("wet side" in industry terminology (Rinsky, Tr. 818-820)) were included in the cohort. Men employed in the Pliofilm operations, but not in production jobs (so called "dry side" workers) were not included in the study. Follow-up of vital status was attempted from termination of employment to June 30, 1975 and was achieved for 75% of the total of 748 benzene-exposed workers. So as not to overestimate the true risk of lymphatic and hematopoietic malignancies associated with benzene exposure, the 25% of the cohort for whom vital status was not determined were assumed to be alive. Little or no quantitative exposure data existed for these plants.

Causes of death were determined from death certificates, and person-years at risk were determined by a modified life-table method. Person-years of observation and causes of death were determined from January 1, 1950 to December 31, 1975. Two control populations were used to generate the numbers of expected deaths in the study. The first comprised the U.S. white male population, while the second was white males employed in an Ohio fibrous glass production facility during the 1940's and who had achieved five years of employment by June 1, 1972.

The most striking finding was the observation of a statistically significant (p less than 0.002) five-fold increased risk of dying of leukemia compared to the U.S. male rates (7 deaths observed vs. 1.38 deaths expected, p less than 0.002), as well as to the fibrous glass workers (7 deaths observed, 1.48 deaths expected, p less than 0.002).

Criticisms of various aspects of this study were raised by participants to the rulemaking. The issue of what level of benzene the workers in the Infante et al. cohort were exposed to was the most discussed area. Participants criticized the information available in the Infante study. The study referred to a November 1946 report of the Industrial Commission of Ohio which indicated that: "Tests were made with benzol detectors and the results indicate that concentrations have been reduced to a safe level, and in most instances range from 0 to 10 or 15 parts per million." Comments at the hearing demonstrated that there were area exposures during this study period exceeding these levels, at times reaching values of hundreds of parts per million. Since no personal monitoring data are available, any conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level.

The study was also criticized for combining the two separate plants in the same analysis. It was suggested that an independent analysis of the two plants would produce different results, thereby suggesting that factors other than similar exposure to a single agent (benzene) contribute to the excess leukemia. (Lamm, Tr. 2538). OSHA believes that the use of non-age-adjusted leukemia death rates, as utilized in Lamm's analysis, is inappropriate for the assessment of an event associated with age. Therefore, OSHA believes that this criticism is unsupportable on this basis. Moreover, the cohorts were combined based on the similarity of the processes in the two plants (Tr. 842). Also, because of the small number of subjects in the study cohort, the authors stated that it would be inappropriate to analyze the data separatedly for the two plants. (Infante, Tr. 935, 796-97).

A question has been raised by industry participants as to the validity of excluding the "dry side" (Pliofilm finishing) workers from the study cohort (Lamm, Tr. 2638-29; API, PC 33, p. 42-43). As explained by one of the authors, these workers were never intended for inclusion in the cohort following discussion with company personnel indicating there was no benzene exposure on the dry side (Infante, Tr. 929-30). Testimony was also offered that if "dry side" employees had job operations which kept them predominantly on the wet side of the plant, then those employes were included in the cohort (Tr. 931). Limited data subsequently released by the University of North Carolina at the OSHA hearing indicated that there may have been some benzene exposure (0, 11.8 20 ppm) on the "dry side". However, there were only 3 sample points and no details were given as to sampling locations, duration of sampling, or definition of departments, to permit interpretation of this information (Ex. 187B.6, Table 3, p. 10). Infante testified that a cursory examination of "dry side" workers revealed no leukemias. However, Infante stated, "• • • there really are not enough people who are employed on the dry side who never went into the wet side to make a meaningful conclusion about that (leukemia deaths from exposure among workers on the dry side)" (Tr. 930). Based upon the above considerations, it appears that the "dry side" workers should not have been included as was the case.

A question was raised as to whether the study demonstrated the true risk of leukemia among workers exposed to benzene (Tr. 311). Sakol referenced two cases of leukemia at the same plant which he personally diagnosed, which were not so certified on death certificates. He cited these cases in support of the substantial underascertainment of leukemia mortality in the study of Infante et. al., due to their sole reliance on death certificates.

The use of the Connecticut Tumor Registry data to determine the expected number of type-specific leukemia deaths for the Infante cohort was criticized. Jandl calculates that the tenfold excess risk of myelogenous and monocytic leukemia found by Infante et. al. may have been off by at most a factor of two. (ORC/Jandl, PC 34, p. 77). (Also, there is a counter-balancing underestimate of the risk because at the time of the report, only 75 percent followup had been completed and the remaining 20 percent of the study population were all regarded in the statistics as being alive at the end of the study period. Both the stengths and weaknesses of the Infante et. al. study have been carefully evaluated by this Agency. OSHA believes this study is one of the more definitive investigations in the benzene literature and provides additional evidence supportive of earlier studies which implicate benzene exposure and the subsequent development of leukemia.

An opposite result was obtained in a Tabershaw-Cooper Associates Inc. mortality study of petroleum refinery workers (Ex. 2-5a). The study population was a sample of workers from the 251 U.S. refineries operating in 1971. The authors attempted to select a sample of 17 U.S. refineries to give a representative distribution with respect to geographic area, ownership, and size. Hourly workers with more than one year of work experience between January 1, 1962, and December

31, 1971, were studied. All workers were classified as to their potential hydrocarbon exposure. The authors reported that better than 94% follow-up was achieved. An excess mortality from lymphoma was observed although it did not achieve statistical significance.

Subsequently, the study was expanded to include 5,145 workers who had been hired on or before 1943 and who were working sometime during January 1, 1962, through December 31, 1971. No excess mortality from leukemia or lymphomas was observed in this subpopulation having 20 or more years since first hydrocarbon exposure. Gaffey, one of the authors of the study, stated that the study had been commissioned not specifically to study the effects of benzene, and in fact he could not delineate what proportion of the study population had ever been exposed to benzene (Tr. 1343-1344). Moreover, as adduced during the hearing, Gaffey acknowledged that there was no industrial hygiene assessment of the work environment (Tr. 1251) to provide the basis for identifying which workers may have been exposed to benzene.

Because this study was designed to assess potential effects of "hydrocarbon" and not benzene exposure and since no group of workers exposed to benzene was clearly identified, this study provides no relevant information as to the leukemogenic risk of exposure to benzene. Therefore, OSHA does not view this study as providing negative proof that benzene does not cause leukemia.

Dow submitted a study which addressed the incidence and mortality of leukemia among benzene-exposed workers (Ex. 154). The mortality experience for all employees occupationally exposed to benzene from 1940 to 1973 was studied. Expected deaths were calculated using age-cause-specific mortality rates for the corresponding U.S. white male population from 1942 to 1972. Each of the 594 workers were classified in approximate benzene exposure categories. A rough cumulative dosage was calculated. When consideration was given to the incidence of myelocytic leukemia, the authors concluded that a statistically significant excess was demonstrated (3 deaths observed vs. 0.8 expected, p less than 0.05) (Ex. 154, p. 12). Mortality data were analyzed by production areas and according to cumulative dosage and length of occupational exposure. Those people in the cohort who had exposures to known carcinogens were excluded from analyses dealing with dose-response in relation to benzene exposure.

An increase in leukemia incidence was observed in the population where 2 deaths were observed vs. 1.0 expected. An additional death resulting from myelogenous leukemia was identified among the study cohort subsequent to the earlier published report. Based upon their findings the authors stated that:

> In these cases, varied work histories, low levels of potential benzene exposure relative to other employees in the cohort, and the lack of information in regard to total medical history made a retrospective assessment of the possible relationship to benzene exposure very judgmental.
> (Ott, Ex. 154, p. 12.)

However, based upon the recent finding of the third death due to leukemia, Dow lowered its internal ceiling limit from 25 ppm to 10 ppm (Ex. 82).

In addition to the 3 deaths reported due to leukemia, 2 deaths attributable to non-malignant blood disorders were also reported: aplastic anemia and pernicious anemia. (OH, Ex. 156, p. 9.) Deaths attributed to aplastic anemia without examination of bone marrow aspirates, may in actuality, be due to leukemia (Vigliani Ex. 2-15, p. 123), thereby potentially resulting in an underestimation of leukemia risk among the benzene-exposed cohort.

OSHA recognizes that the decedents were for the most part exposed to relatively low concentrations of benzene, and no leukemia deaths occurred in the higher exposure groups. However, because of the small population size as well as the possibility of sensitivity of those individuals developing leukemia, it cannot be concluded that these deaths are not caused by benzene exposure.

OSHA does conclude that the findings of this study are consistent with the findings of many studies that there is an excess leukemia risk among benzene exposed employees.

Allied Chemical Corp. submitted a post-hearing comment containing mortality data for employees with potential benzene exposure (P.C. 22). Death certificates were obtained for all workers dying between 1961 and mid-1977. Rough exposure information was derived by back extrapolation, limited exposure data, and subjective reports of employees regarding signs and symptoms. Based on these estimates of benzene exposure, there was no observed cluster of leukemia in operations having benzene exposure. Because this study was presented to OSHA after the hearing closed, more specific details concerning the estimate of exposure, the method utilized for obtaining estimates of person-years at risk, or how the death certificates were coded were not obtained.

In 1974, Thorpe reported that the incidence of leukemia, among a population of 38,000 workers exposed to low levels of benzene over a ten year period (1962-1972), was not statistically different from that expected on the basis of the general population (Ex. 2-34). However, the study has been criticized for the relaxed casefinding techniques and analytical methods (Brown, Ex. 2A-35). Thorpe himself acknowledged the following serious methodologic deficiencies:

1. Validity of leukemic diagnoses.
2. Quantitative determination of exposure levels.
3. Adequacy of retiree follow-up.
4. Complete occupational histories.

As in the case of the Tabershaw/Cooper study, OSHA cannot separate the benzene-exposed workers from those with little or no exposure. This difficulty, compounded by the 4 deficiencies listed above, also precludes reliance upon the finding of the Thorpe study.

University of Pittsburgh investigators (Lloyd, Redmond, Ex. 113) have published a notable series of epidemiological studies of steelworkers mortality. AISI (P.C. 36, pp. 59-60) cited the above studies as evidence of no leukemia risk among benzene-exposed coke oven workers. Most notably, the industry cited the fact that byproduct plant coke oven workers were not found to have been at excess risk (P.C. 36, p. 60) and recommended that coke ovens be excluded from the benzene standard (P.C. 36, p. 100).

However, as Bickmore stated:

> • • • In all 35, the expected, the incident (SIC) of mortality and expectation is so low as to preclude any meaningful statistical calculations by the professionals that made the study. (Tr. 3314)

These coke oven worker studies were designed to assess worker risk of exposure to coke oven emissions (Ex. 113 p. 1) (P.C. 27C p. 1, P.C. 27D p. 1). Given the small numbers of observed and expected rates of leukemia, and in the absence of a study designed to assess coke oven worker exposure to benzene, OSHA believes it inappropriate to rely on these studies as evidence that there is not a leukemia risk of exposure to benzene.

During the hearing, Stallones discussed the unpublished study of 3,600 Shell Oil Company workers with "potential" benzene exposure (Ex. 115C.2). Among this population he testified that he observed no excessive leukemia mortality in the three year period ending in 1976. Stallones could not determine how many workers were exposed to benzene. In fact, clerks and officer workers were included in the study group. Again, failure to correctly identify or define a benzene-exposed cohort limits the usefulness of this study.

A series of published and unpublished epidemiologic studies investigating the mortality experience of rubber workers have been entered into the hearing record. (McMichaels et al. Ex. 2-36, -37, 2B-295); Monsan and Nakano (Ex. 2-83); Fox et al. (Ex. 2-61); Andjelkovic (Ex. 2-54); Occupa-

tional Health Studies Group, UNC (Ex. 187.B). These studies have, in general, shown excess of lymphoma and leukemia among rubber workers. The leukemia was predominantly lymphatic, a cell type not commonly associated with benzene. The proportion of rubber workers actually exposed to benzene in these studies is undetermined. The presence of other chemical exposures raises the question of an alternative causative agent for the excess of lymphatic leukemia and lymphoma observed among rubber workers. In view of these considerations, these studies provide no additional evidence for the leukemogenic potential of benzene.

There has been discussion whether benzene is a *primary carcinogen* (can directly effect a neoplastic alteration without host-mediated activation); a *secondary carcinogen* (chemicals which may increase susceptibility of cells, to a primary carcinogen); a *procarcinogen* (requires biochemical alteration prior to effect); or a *co-carcinogen* (which requires the interaction of another chemical to elicit a neoplastic response). (Olson, Tr. 2892; NRC, Ex. 2-4, p. ii; API/NPRA Brief, P.C. 33, p. 86-87; Aksoy, Tr. 177; Furst, Tr. 1744; Stockinger; P.C. 32-H, 53); Weisburger, P.C. 32-I; Tabershaw Tr. 2549, 2545). The evidence is, at present, insufficient to choose among these alternatives. Namely, what is apparent, however, is the effect of benzene exposure—a significantly increased risk of death from leukemia.

Types of leukemia clearly associated with benzene exposure include acute myelogenous leukemia (AML) and its variants. For example, Aksoy testified that among 40 cases of leukemia among benzene-exposed workers in Turkey, AML and its variants were the most frequently observed form (Ex. 60, p. 7). In the experience of Vigliani and his coworkers, only acute or subacute myelogenous leukemias were observed (Ex. 2-49). The predominant cell type found by Infante (Ex. 2A-271) and others were also myelogenous in character. This well-established association between benzene and AML is in concert with the well-known toxic effects of benzene on bone marrow stem cells (Goldstein, Ex. 43B, p. 162).

In contrast to the definitive relationship between benzene and the induction of AML and its variants, there is considerable scientific debate concerning the association between benzene exposure and the development of chronic forms of leukemia (CLL and ML). Jandl has stated that "* * * lymphoid leukemia is not a feature of benzene toxicity." (ORC/Jandl, P.C. 34, p. 59), and Lamm ruled out chronic leukemia, not as a "possibility", but as a "probability" (Tr. 2558). Aksoy found no cases of CML among the workers he studied. (Ex. 60, p. 6-F), and no cases of CLL were seen by the Italian investigators. A different result has been reported by several French studies which have reported a relatively high incidence of CLL. In some instances, there were more cases of CLL than AML. They also report a higher incidence of CML than would be expected based on Aksoy's and Vigliani's findings. Supporting the high incidence of CLL in the French studies is the report by Tarreef which describes 16 cases of leukemia which resulted from long-term exposure to benzene, 3 diagnosed as CLL (Ex. 2-28).

The evidence is inconclusive as to the relationship between benzene exposure and the development of forms of leukemia other than AML and its variants. Vigliani stated (1976) that, although he did not observe chronic leukemias in his series, "there is no *a priori* reason for not accepting them as benzene-induced leukemias * * *" (Ex. 2-49, p. 148). OSHA believes at this time that it is prudent to recognize the possibility that benzene exposure may be related to chronic forms of leukemia.

One of the major issues of this rulemaking is whether a blood disorder is a necessary precursor for the subsequent development of leukemia. For example, in 1974 NIOSH speculated as follows:

> It can be postulated that bone marrow changes and blood dyscrasias would precede leukemia if induced by benzene, so that if these changes were prevented leukemia should not result (Ex. 32B).

Aksoy has testified that benzene leukemias usually develop after a previsous pancytopenic period. (Tr. 198) Maugeri, reports that, "the leukemias in our cases were always of the acute, aleukemic slow developing type, and they were always preceded by [an] aplastic condition" (Ex. 39-10, p. 2). Snyder remarked that he was unaware of benzene leukemias without previous demonstration of some kind of bone marrow damage (Tr. 3226) and Goldstein has noted that, "there does not appear to be any proven cases of leukemia in the absence of previous pancytopenia" (Ex. 43B, p. 165). But Goldstein cautions that this interpretation is, "open to speculation, especially in view of the paucity of routine laboratory data preceding the onset of leukemia" (Ex. 43B, p. 165).

As observed by Goldstein, since the mechanism by which benzene induces leukemia has not been elucidated, it is possible that leukemia develops, not in response to the pancytopenic effects of benzene, but rather to the direct carcinogenic effect on the marrow hematopoietic stem cells not necessarily accompanied by any other evidence of marrow effect (Ex. 75, p. 3). In such events, protection against non-neoplastic blood disorders would not rule out subsequent development of leukemia.

Vigliani, in discussing the evidence causally relating leukemia to benzene exposure observed that such leukemia may occur, "* * * directly or following aplastic changes in the bone marrow * * *" (Ex. 2-49, p. 148). In response to a question concerning whether aplastic anemia is a necessary precursor for leukemia, Lamm responded in the negative (Tr. 2562). Also, Browning in 1965 observed that, "benzene leukemia is frequently superimposed upon a condition of aplastic anemia, *but it can develop without a preceding peripheral blood picture characteristic of bone marrow aplastia* (emphasis added) (Ex. 2-31).

Finally another industry participant was reluctant to conclude that cytopenias "always" precede leukemia (Tabershaw, Tr. 2546). The evidence is not conclusive. There has been no scientific study of leukemia and preceding pancytopenia resulting from low levels of benzene exposure. The current lack of a reproducible benzene leukemia animal model forecloses the use of experimental evidence. There is no agreement on prospective criteria for benzene-induced blood abnormalities. Therefore, the statement that non-malignant pathological changes always precede leukemia is essentially based on retrospective analysis. The fact that non-malignant blood changes may occur shortly (within a few months) after first exposure to benzene, while leukemia may appear as long as 10 years or more after initial exposure suggests that separate etiologic pathways may be involved.

A corollary issue related to preceding blood disorders is whether recovery from such abnormalities eliminates the risk of leukemia deaths attributable to benzene exposure. Rosen has stated that: "[w]hether reversing the early toxicity can prevent the development of more serious blood dyscrasias in some cases is open to question, but it is a definite possibility" (Ex. P.C. 26A, p. 4).

> Jandl has written: "In carefully studying other reports of long latent periods, or of any period between an initial aplasia and a terminal leukemia in which the patient was hematologically normal, I failed to find any well-documented example of complete recovery followed years later (despite abstinence from benzene exposure) by acute myelogenous leukemia" (ORC/Jandl, P.C. 34, p. 24).

Because of the lack of information with a suitably identified cohort followed for a sufficient number of years, it is impossible to make a determination whether or not these "recovered" workers are actually at increased risk of dying of leukemia. This uncertainty has been expressed in the conclusions in the Dow Chemical Company morbidity studies:

> The question that remains unanswered, because of the relatively small sample size

of this study, is what is the probability that serious effects of benzene (such as leukemia) will appear years after first exposure and after a period of health surveillance during which no hematological abnormalities are noted (Dow/Fishbeck, Ex. 154, p. 19).

OSHA agrees with the caveat expressed by Dow, and therefore the benzene regulation is not predicated on reversal of blood abnormalities protecting against the development of leukemia.

Benzene-associated leukemia is frequently characterized by a long delay between initial exposure and the onset of disease. Sellyei and Kelemen report a case of subacute granulocytic leukemia in a patient 8½ years after starting to work with benzene (Ex. 2B-258). Hernberg reported a case of a 10-year period between initial exposure and the onset of leukemia in a woman with normal interval blood counts who was exposed to benzene for a total of 6 months (Ex. 217-152). In 1974, a case of acute leukemia was observed in a woman who, following a benzene-induced anemia, was reported to have an exposure-free period of 14 years with almost normal blood counts (Vigliani and Saita, Ex. 2-50, p. 214). Infante et al. report a range of 2-21 years between initial exposure and death; all but one exceeded 10 years (Ex. 2A-272). Goldstein hypothesizes that if benzene-induced hematologic damage is expressed by an * * *

aberration in the bone marrow producing a stem cell that is liable to a further mutagenic event, such an event could conceivably occur many years after the original insult. (Ex. 43B, p. 166).

The delay in the expression of overt disease is a characteristic of many other carcinogenic compounds. With regard to benzene, it has been documented that there is a relatively rapid decline in the incidence of leukemias following cessation of worker exposure to benzene. Aksoy has testified that after the substitution of other solvents for benzene, there has been a decline in the annual number of workers diagnosed with benzene-leukemia (Ex. 60, p. 3). Vigliani and Forni reported that there was a sharp decrease in cases of chronic benzene poisoning after the use of benzene as a solvent was banned (Ex. 2-50, p. 214). These observations appear to be paradoxical in light of the latency periods also reported. However, Forni and Vigliani have noted that, occasional cases of acute leukemia with a long latency period may still be observed (Ex.2-50, p. 215) and Aksoy, while reporting that no additional cases of leukemia among shoeworkers were diagnosed in 1976, noted that this did not preclude the development of additional cases in the future (Tr. 169).* The question of latency periods for benzene-induced leukemias has not been resolved and requires further investigation.

Another area of discussion is the question of identifying individuals who may be particularly sensitive to the hematotoxic effects (including the development of leukemia) of benzene. Several witnesses including industry participants generally expressed the view that there probably were differences in sensitivity (Sakol Tr. 228; Shaw Tr. 412; Snyder Ex. 54.2, p. 25, Thorpe, Eckard Tr. 2052; Furst Tr. 1791-42). It appears from the evidence that there are individuals in given populations who may, because of genetic factors and/or concurrent or prior exposure to other environmental agents, be especially sensitive to benzene-induced blood disorders.

Aksoy and his colleagues reported a possible familial link in benzene-induced leukemias in 5 of 40 workers indicating a possible genetic predisposition to benzene's harmful effects (Ex. 60, pp. 8-10). Also, Jandl on the basis of tentative data has attempted to identify a subpopulation with risk factors predisposing to increased sensitivity to benzene (ORC/Jandl, PC 34, pp. 43-44). These include:

a. Those between the ages of 16 and 30;

b. Those with prior exposure to benzene or exposed to radiation in excess of that required for diagnostic purposes, and;

c. Those with evidence of a history of other less severe myeloproliferative disorders such as remitted aplastic anemia, certain abnormal circulating blood cells, or those with persistent abnormalities in one or more blood cell types.

Other predisposing factors may include exposure to drugs or alcohol which may act to modify the metabolism of benzene. These postulated effects are not consistently observed or universally accepted by investigators. In his testimony, Shaw stated that there was no way to determine who is susceptible to benzene and who is not (Tr. 420). And despite "well substantiated information" concerning the increased sensitivity of certain groups to benzene, the International Workshop was unable to develop and provide specific guidelines on this matter (Ex. 17, p. 7). These sensitive individuals, interspersed among the working population, are certainly among those who are at highest risk of material impairment from benzene exposure. The size of this group is unknown. It is the purpose of this regulation (especially the permissible exposure level and detailed medical surveillance protocol) to not only minimize harmful effects of benzene exposure, but also provide early diagnosis and treatment should such effects occur.

c. Animal studies. The wide variety of non-malignant hematological disorders observed in humans exposed to benzene which range from simple anemia, and leukopenia to aplastic anemia have been experimentally induced in animals. However, attempts to demonstrate the development of leukemia in animals exposed to benzene has met with less success. Until recently, a study by Lignac in 1932 was the only animal study known to OSHA in which leukemia has been observed in animals exposed to benzene. (Ex. 2-38). Fifty-four mice (28 females; 26 males) were given subcutaneous injections of benzene (0.001 ml in 0.1 ml of olive oil) for 17 to 21 weeks. Nine mice were initially excluded following intercurrent infection and an additional 12 were lost through atrophy of various organs, especially the spleen. Lignac attributed these 12 deaths to the size to the dose of benzene. Eight of the remaining 44 mice developed leukemia or Kundrat's lymphosarcoma and died 4 to 11 months after receiving the first injection. The absence of concurrent controls makes interpretation of the results problematic and uncertain. Failure to identify the mouse strain studied has frustrated efforts to independently confirm the findings.

Other studies have failed to reproduce Lignac's results. Amiel in 1960 utilized four inbred strains of mice and subjected them to the same experimental program outlined in Lignac's study. (Ex. 2-39). No leukemic or aplastic hemopathies were observed. Ward et al. administered benzene subcutaneously to a strain of mice which is known to be responsive to leukemogenic agents. (Ex. 2-40). A slight increase in the percentage of granulocytic leukemias was observed in the benzene-treated mice as compared with the controls; however, the authors viewed the increase as not statistically significant.

In a letter transmitted Aug. 9, 1977 to Eula Bingham, Asst. Secretary of Labor, Nelson described preliminary results of an inhalation experiment using rats and mice (Ex. 178). Animals were exposed to benzene vapors 6 hours per day, 5 days per week for up to 2 years. Two possible leukemias were observed in a group of 40 strain CD mice exposed to 300 ppm. In one animal, elevated WBC counts were observed 193 days after exposure, with death following 3 days later. The autopsy findings were consistent with CML, a disease not known to arise spontaneously in this strain. The second mouse exhibited the presence of abnormal blast forms in the peripheral blood after 211 days of exposure and died 4 days later. Whether this finding indicates AML, a disease previously observed in this strain, or acute lymphoblastic or stem cell leukemia (spontaneous incidence about 4 per-

*A short latency resulting from high exposures is another possible explanation.

cent) had not been resolved at the time the report was submitted.

One of the 40 rats exposed to 100 ppm benzene developed an elevated WBC count after 240 days of exposure with the cell counts continuing to increase slowly. Peripheral blood smears showed some immature neutrophils. This finding is compatible with a diagnosis of CML, a disorder which is relatively rare for the rat. However, a non-leukemic leukemoid process could not be excluded.

Nelson characterized the results of the study as:

> * * * slender evidence of the production leukemia. Nevertheless, despite the shakiness, we believe these results to be extremely suggestive and provide an urgent basis for intensive further study (Ex. 178).

D. *Conclusions.* Leukemia is a serious world-wide problem. In this country alone, approximately 20,000 adults die annually from this disease, and about 12,000 individuals develop and die from AML each year (ORC/Jandl, P.C. 34, p. 72). However, based on the published literature the number of AML deaths attributable to benzene exposure is unknown. In this regard, Goldstein states: "The incidence of leukemia appears to be a small fraction of all benzene-induced hematotoxicity." (Ex. 54.B, p. 160). One reasonably complete 9 year follow-up study of 147 workers exposed to benzene, of which 109 displayed some degree of cytopenia, 1 case of leukemia was observed (Hernberg et al., Ex. 2-252). Dr. Jandl observes that, "* * * few patients with proven cases of acute myelogenous leukemia can be discovered in the American literature in the past 10 years * * *." However, the unusual number of erythroleukemias observed by Sakol at the Akron Pliofilm operation (Sakol, Ex. 61) indicates that there may be a severe underreporting of benzene-induced leukemias. Also, the relationship between initial leukemia and exposure to benzene may be less apparent than the benzene-induced cytopenias due to the substantial delay between exposure and manifestation of symptoms (Goldstein, Ex. 43.B, p. 160). Moreover, in many such instances the victim may be unaware of earlier exposure.

When case reports are derived from patients who are sufficiently sick to seek medical attention, the relative prevalence of leukemia is reported to be much higher. For example, in the 1976 report by Vigliani and Forni in which a total of 83 compensation cases of benzene toxicity were observed, leukemia accounted for 19 (Ex. 2-15).

Vigliani has estimated based upon available literature, that the number of cases of leukemia attributed to benzene exposure is "at least 150" (Ex. 2-49, p. 144). The document, "Benzene in the Work Environment", used to establish the German Occupational Standard, summarized over 250 reported cases of leukemia in individuals who had been chronically exposed to benzene. (Ex. 2-58). Jandl states there have been at least 250 cases of AML in the United States which are believed to be the result of exposure to benzene. (ORC/Jandl, PC 34, p. 103). It is impossible to extrapolate these published findings to either an absolute total or a relative incidence. Beyond the likely underreporting of cases, the incidence of benzene leukemia may be greater than previously recognized since many diagnoses were made without results of marrow aspirates. Thus, peripheral pancytopenia may have been inaccurately labelled aplastic anemia when marrow examination might well have revealed acute myeloblastic leukemia, leukopenic or aleukemic leukemia, a type characterized by a decline in circulating white cells. (Vigliani, Ex. 2-49, pp. 143-4).

The evidence in the record conclusively establishes that benzene is a human carcinogen. The determination of benzene's leukemogenicity is derived from the evaluation of all the evidence in totality and is not based on any one particular study. OSHA recognizes, as indicated above that individual reports vary considerably in quality, and that some investigations have significant methodological deficiencies. While recognizing the strengths and weaknesses in individual studies, OSHA nevertheless concludes that the benzene record as a whole clearly establishes a causal relationship between benzene and leukemia.

The evidence indicating that relationship has been expanding and the international scientific community has increasingly acknowledged that worker exposure to benzene is associated with an increased risk for the induction of leukemia, in fact, today there is little dispute that benzene is a human leukemogen.

For example, in 1976 NIOSH stated:

> NIOSH considers the accumulated evidence from clinical as well as epidemiologic data to be conclusive at this time that benzene is leukemogenic. Becauses it causes progressive, malignant disease of the blood-forming organs, NIOSH recommends, that for regulatory purposes, benzene be considered carcinogenic in man (Ex. 2-5).

In a paper presented at the International Workshop, Brair wrote that:

> It is now generally recognized that benzene leukemia is a nosological entity. (Ex. 34-5, p. 4).

Vigliani has observed:

> [F]rom the vast literature accumulating over the last forty years, the conclusion can be drawn that the clinical as well as epidemiological data are indicative of a strong leukemogenic action in man * * * (Ex. 2-49, p. 148).

Aksoy testified that:

> [T]here is overwhelming scientific evidence that benzene can cause leukemia in man (Tr-144).

Other witnesses and commentators were in basic agreement with this conclusion: (Goldstein, TR-351, 389; Sakol, TR-316; Jandl, P. C. 26B. Addendum V, P. V, Tabershaw Tr 2545).

In 1971, the Senate of the Deutsche Forschungsgemeinschaft for the Examination of Hazardous Industrial Materials indicted benzene as a human carcinogen (See NIOSH Ex. 84A, p. 1). Two years later, Eckardt, then Medical Director of Exxon Corp., stated,

> [t]he accumulated evidence in the literature leads to the inevitable [sic] conclusion that benzene is a leukemogenic agent, particularly in cases that have previously displayed a panmyelopathy. Although this had long been suspected, the data reported in the literature was not sufficiently convincing to establish the leukemogenic nature of benzene. However, the more recent observations seem to establish the association beyond a doubt (Ex. 84, B.2., p. 7).

Industry participants in the benzene rule-making did not, for the most part, challenge benzene's leukemogenicity. Rather, they argued that there is a threshold level for benzene and that, consequently, benzene is not a leukemogen at low levels. In support of this argument, industry cited several epidemiological studies purporting to demonstrate that an excess risk of leukemia is not seen in workers exposed to benzene at levels lower than 10 ppm. Although the epidemiological method can provide strong evidence of a causal relationship between exposure and disease in the case of positive findings, it is by its very nature relatively crude and an insensitive measure. In the case of negative findings, the results are especially difficult to interpret for several reasons. One methodological artifact commonly observed is the failure to adequately define the composition of the study cohort. The fundamental premise of any epidemiological investigation of the potential relationship of occupational exposure to an agent and observed health effects is, in OSHA's view, a careful definition of an exposed cohort. As was pointed out above, many of the benzene studies cited by industry suffer from this design defect. Other factors, such as incomplete followup of workers who may exit the cohort and uncertainly as to the actual cause of death lead to further dilution of the reported results. The presence of a latency period exacerbates this problem: The long delay between exposure and manifestation of symptoms, compounded by the high mobility of our society make it medically and scientifically extremely difficult to identify workplace carcinogens. An additional difficulty arises from the apparent variability in individual sensitivity. Epidemiological study populations tend to be small and reaction to an etiological agent may not appear in the cohort, due to varying degrees of sensitivity. On the other

hand, positive retrospective investigations suffer from these artifacts to a much lesser degree. For these reasons, it is OSHA's policy when evaluating negative studies, to hold them to higher standards of methodological accuracy.

As stated above, the positive studies on benzene demonstrate the causal relationship of benzene to the induction of leukemia. Although these studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers. The Agency, however, recognizes that not all individuals exposed to benzene will suffer harmful effects. The benzene record establishes that there may be individual effect levels. However, there is no way of ascertaining which workers in any exposed population are susceptible and to what levels.

OSHA further recognizes that determinations of carcinogenicity are normally based on animal studies, and when available, human evidence. OSHA acknowledges that, at the present time, there is no unequivocal animal model demonstrating the induction of leukemia. However, the lack of an animal model does not diminish the conclusive nature of human evidence demonstrating benzene's leukemogenicity.

OSHA acknowledges that there are many unresolved issues concerning the relationship between benzene exposure and leukemia:

Whether benzene is a co-carcinogen, a procarcinogen, etc.

Whether benzene exposure is causally related to induction of forms of leukemia other than AML and its variants.

Whether blood dyscrasias, such as aplastic anemia always precede benzene leukemia.

To what extent are leukemia deaths attributable to occupational exposure to benzene.

What factors identify a sensitive population.

These questions are on the frontier of scientific and medical knowledge and, given the mandate of the Act, OSHA cannot wait for answers while workers are exposed to this life—threatening substance. There is no doubt that benzene is a carcinogen and must, for the protection and safety of workers, be regulated as such. Given the inability to demonstrate a threshold or establish a safe level, it is appropriate that OSHA prescribe that the permissible exposure to benzene be reduced to the lowest level feasible.

4. *Chromosome studies.* OSHA has examined both the original literature of benzene-induced chromosomal changes and the material contained in recent reviews of the subject (NRC Report, Ex. 2-4, section entitled: Chromosome Effects; Forni, Ex. 156.H and; Wolman, NYU Report Ex. 43.B, Chapter VI). Evidence derived from human studies together with similar results obtained from experimental investigation clearly demonstrates that benzene can induce visible damage to chromosomes in lymphocytes and blood-forming cells. For example, Tyroler noted that: "I think there is rather convincing evidence that the chromosomal aberrations are associated with exposure to benzene." (Tyroler, Tr. 3100; also see International Workshop, Ex. 17, p. 6). The effects may be manifested as numerical alterations and/or structural rearrangements of the chromosomal material and include additions or deletions of chromosomes, segments of whole chromosomes or chromosome sets, in addition to exchanges which result in morphologically aberrant chromosomes (Wolman, NYU Report, Ex. 43.B, p.—). Forni has observed that the aberrations produced by benzene exposure are non-specific and are similar to those produced by ionizing radiation. (Ex. 156.H). To what extent these events are detrimental to human health is not known.

a. HUMAN STUDIES

There are numerous reports on chromosomal evaluations in worker populations both with and without clinical symptomatology resulting from exposure. In general, these studies reveal that there are statistically significant increases in chromosomal damage in those occupationally exposed to benzene. The chromosome alterations have been classified as either unstable changes (i.e., fragments, dicentric, tricentric and ring chromosomes) and stable changes (i.e. abnormal monocentric chromosomes due to deletions, translocations, inversions and trisomies). Aneuploidy (abnormal chromosome number) and/or polyploidy (a multiple chromosomal set) have also been observed. The early reports focused on the examination of workers exhibiting benzene hemopathy (a disease of the blood). As early as 1964 Pollini and Columbi published such a study. (Ex. 2-17). Examination of cultured bone marrow cells and peripheral lymphocytes showed increased frequencies of aneuploid cells and structural aberrations. A second study by the same group (Ex. 2-4, reference 50) of 4 patients with temporary or progressive blood dyscrasias revealed that the incidence of heteroploid (abnormal number) chromosomal patterns ranged around 70% both in the blood and in the marrow of each subject. The authors were, however, unable to establish a correlation between the duration and degree of exposure and either the frequency of chromosome aberration or the degree of toxicity. Other cytogenetic studies of subjects with benzene-related hemopathies have yielded similar findings (e.g. Forni and Moreo, Ex. 2-18 and 2-19, Sellyei and Keleman, Ex. 2A-258; Aksoy et al., Ex. 2-57; and Erdogan and Aksoy, Ex. 2A-192). Variables which make these case reports difficult to interpret and compare include: differential diagnoses, the use of lymphocytes artifically stimulated to grow in some cases and bone marrow cells in others; the occasional lack of "normal" baseline chromosomal breakage frequency; and the occurrence in some cases of pre-existing familial chromosome aberrations (Wolman, Ex. 43-B, p. 129). In spite of the limitations of these reports, Wolman has stated that some trends have been observed—additional chromosomes have been identified in several reports, tetraploidy (4 sets of chromosomes) or polyploidy were seen in some cases and in many instances an increased frequency of chromosome breakage was reported but not well documented. Wolman states that:

> the clearest picture of the relationship between benzene exposure and chromosomal changes emerges, not from experimental studies or reports of human disease, but from studies of occupationally exposed workers (Ex. 43.B, p. 130).

The National Research Council (Ex. 2-4) considers the 1969 study by Vigliani and Forni (Ex. 2-20) to be one of the most systematic of this type reported. The results of cytogenetic analysis of 25 subjects who had recovered from benzene hemopathy were compared to the findings of controls matched for sex and age. In most cases, increased ratios of both stable and unstable chromosome aberrations were still present several years after cessation of exposure to benzene and/or recovery from poisoning, whereas the hematological analysis revealed normal blood counts in most cases. Follow-up cytological analyses of these subjects showed an overall decrease in unstable changes, and generally, a persistence or an increase in stable alterations. Other cytogenetic surveys of workers industrially exposed to benzene are: (Forni et al., Ex. 2-20; Girard et al., Ex. 2-40; Hartwich and Schwanitz, Ex. 217-129; and Vigliani and Forni, Ex. 2-14).

OSHA is also aware of several cytogenetic studies of workers chronically exposed to airborne concentrations of benzene probably less than 25 ppm. Several indicate an increase in chromosomal damage (Hartwich and Schwanitz, Ex. 129; Girard et al., Ex. 2-65 or 2-283, and Berlin et al. Ex. 2A-218) while others present negative findings (Forni, Ex. 156.H; Tough et al., Ex. 2-21B, and Burgatti, Ex. 2A-226).

b. EXPERIMENTAL STUDIES

The quantity of data available from experimental studies is less than that reported for exposed workers, but it provides additional corroborative evidence that chromosomal aberrations can be induced by benzene. An in vitro study utilizing cultured human lymphocytes, incubated with benzene, revealed that the frequency of chromatid-type aberrations increased with increasing dosages of benzene. It was further observed that the yield of dicentric and ring chromosomes induced by benzene damage was synergistically related to treatment with radiation. A high incidence of chromosomal damage has also been observed in cultured human leukocytes and Hela cells incubated with benzene (Koizumi et al., Ex. 2B-298). In 1970, Philip and Jensen reported that rats acutely intoxicated with subcutaneous injections of benzene displayed increased rates of chromatid breakage in direct bone marrow preparations 12 and 24 hours after injection, followed by a return to normal cytogenetic findings at 36 hours (Ex. 2-23). It has also been reported that rabbits made pancytopenic by chronic exposure to benzene via injection exhibited a high frequency of both chromatid and chromosome aberrations, in uncultured bone marrow cells (Ex. 2-22). After reviewing the animal evidence, OSHA concurs with Wolman's following conclusion:

[T]hat although it appears that exposure times in different species can induce increases in chromosome aberrations, there is no clear evidence for a dose-dependent response to benzene exposure. (Ex. 43B).

c. DISCUSSION

While the record clearly demonstrated that benzene causes chromosomal aberrations, it is equally clear that there is no unanimity of opinion as to what the benzene-induced chromosome aberrations mean in terms of demonstrable health effects, especially the relationship of chromosome damage to the induction of leukemia. For example, the International Workshop concluded: "The implication of the finding of increased chromosome aberrations for the occurrence of benzene leukemia is still not clear." (Ex. 17, p. 6).

Whether these aberration are, in some instances, (1) causally-related to the development of leukemia, or (2) are secondary to the neoplastic state and therefore are epiphenomena of metabolic alterations resulting from abnormal growth is not known (Sandberg, Ex. 2-102).

There are several theoretical considerations and some evidence supportive of the first alternative: Some investigators view chromosomal damage as a mutational event or an event which increases the probability of a mutation (e.g. Wolman, Ex. 43B, p. 126). As the induction or the maintenance of a neoplastic (cancerous) transformation results most probably from a somatic mutation, damage to chromosomal material may enhance the opportunity for such a cellular change to occur. Other interrelated hypotheses in support of a causal relationship between chromosomal damage and leukemia are:

(1) That benzene might induce various types of chromosomal aberrations and that leukemia might evolve in those cases where a potential leukemia clone with a selective advantage develops in response to benzene exposure (Vigliani and Forni, Ex. 2-14).

(2) That cells exhibiting chromosomal instability or imbalance may be more susceptible to transformation by a leukemogenic virus (International Workshop, Ex. 17, p. 6) or;

(3) That chromosomal aberrations may lead to decreased immunological surveillance, and that in such instances, leukemia can develop if abnormal cell clones (some of which may be neoplastic) are not eliminated. In this context, Forni and Moreau reported a case of a benzene-induced leukemia in which both bone marrow and peripheral lymphocytes exed 47 chromosomes (1 more than normal) with the same karyotype, suggestive of clone formation. (Ex. 2-18).

There are also several investigators who believe that at this time, there is insufficient evidence to establish a causal link between visible chromosomal damage and leukemia (Ex. 156.2). For example, Snyder has stated that:

while exposure to benzene in sufficient concentration and for extended periods of time has been linked with both chromosomal aberrations and leukemia in humans, benzene-induced chromosome damage has been found in individuals who have not exhibited leukemia * * * (p. 22).

Additional evidence in favor of the non-causal relationship nature between chromosomal damage and leukemia was presented by Jandl. He observes that exposure to several types of agents, not known to possess leukemogenic action, induce chromosomal abnormalities which may persist for months.

Sandberg cautions that no consistent karyotypic pattern has emerged for any type of cancer or leukemia and in about half of all cases of acute leukemia, some cases of chronic myelogenous leukemia and in almost all cases of chronic lymphocytic leukemia, no visible chromosomal alterations occur (Ex. 2-102). And also, Elkins feels that the evidence fails to establish a causal link between chromosome alterations and leukemia (Ex. 156C, p. 22-23).

Whether these gross alterations of chromosomes can be viewed as toxic or mutational events depends on the fate of the affected cell. If the alteration in the chromosomal material results in an inhibition of further cellular division, then in terms of its reproductive potential, the cell is dead and the damage inflicted may be classified as a toxic event. However, if the damage does not interfere with the reproductive ability of the cell, and the alteration is replicated, this may constitute a persistent gross mutation, "* * * a structural change in the genome which presumably alters cell function". (Wolman, Ex. 43.B, p. 126.) In addition to structural and numerical alterations, benzene has been observed to induce chromosomal breaks:

While breaks may be repaired and are not necessarily mutational events (in the sense of being inherited), each occurrence increases the probability of a structural aberration and, therefore of a mutation (Wolman, Ex. 43.B, chapter VI).

In viewing benzene as an agent potentially capable of interacting with the genetic material, several points should be made:

(1) All of the studies demonstrating benzene's "clastogenic" or chromosomal-damaging effect (Shaw, Ex. 2-94) have apparently reported the effects in somatic cells only. In view of the wide distribution of benzene in the body, it is not unreasonable, however, to assume that given somatic chromosomal damage resulting from benzene exposure, that germinal tissue may also be affected. In her review of clastogenic substances, Shaw has stated:

Because changes in the genes and chromosomes do not usually produce an immediate health hazard, they may go undetected for a lifetime or even for several generations. Yet, the human gene pool can become insiduously polluted. (Ex. 2-94, p. 409).

(2) Despite the considerable evidence demonstrating benzene's ability to inflict visible damage to chromosomes, benzene has not manifested mutagenic activity when tested in various microbial assay systems (Kraybill, Ex. 84. B 19, p. 314).

(3) The finding of gross chromosomal damage in bone marrow cells clearly demonstrates that despite competing detoxification reactions (see: Olson, Ex. 149, p. 12) benzene, or a reactive metabolite, is able to overwhelm protective defense mechanisms and enter the nucleus of hematopoietic cells.

In summary, the evidence clearly demonstrates that benzene is capable of causing significant increases in chromosomal aberrations in somatic blood cells in the absence of clinical and/or hematological symptomatology. It is also clear that for man, no quantitative dose-response relationship has been established for these effects. It is OSHA's interpretation of these findings that chromosomal damage represents an adverse biological event of serious concern which

may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene.

V. Economic Considerations

In setting standards for toxic substances, the Secretary is required by section 6(b)(5) of the Act to give due regard to the question of feasibility. Section 6(b)(5) mandates that final standards be set which most adequately assure employee safety and health "to the extent feasible, on the basis of the best available evidence" and further requires that, in the development of occupational safety and health standards, "considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts. *Industrial Union Dept., AFL-CIO* v. *Hodgson*, 499 F. 2d 467 (C.A.D.C., 1974); *AFL-CIO* v. *Brennan*, 530 F. 2d 109 (C.A. 3, 1975). As pointed out by the D.C. Circuit Court of Appeals, Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, "standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely; further, the Court said, the concept of economic feasibility does not "necessarily guarantee the continued existence of individual employers." *Industrial Union Dept., AFL-CIO* v. *Hodgson*, supra, at page 478.

In accordance with the Secretary's position, it has long been OSHA's practice to analyze the economic feasibility of proposed standards where significant economic impact on employers covered by the proposals seem likely, to make such analysis available to affected parties for comment and subsequent hearing prior to issuance of final rules, and to invite the submission of other information on the economic impact and feasibility of proposed standards. In developing a final standard, therefore, OSHA evaluates the economic feasibility of the final standard on the basis of the information developed by its own studies of the proposal and submissions by the public during rulemaking.

To assess the economic feasibility of the proposed standard for benzene, OSHA undertook an extensive study of the proposal's economic impact on various affected industries. This study was conducted for OSHA by Arthur D. Little, Inc. (ADL). (Ex. 5A, 5B). The ADL study has provided basic economic data for the evaluation of the economic impact of the permanent benzene standard on the major affected industries. Additional information for this purpose was obtained through OSHA's analysis and consideration of all other economic data, comments, arguments and testimony submitted at the benzene hearing, in pre hearing comments and in post-hearing comments and briefs. On the basis of the best available evidence, therefore, OSHA has determined, as explained in detail below, that the permanent benzene standard is economically feasible.

Compliance Costs

Estimates of total costs of compliance with the permanent benzene standard for the major affected industries studies are as follows: First year operating costs for all industries combined are estimated by OSHA to be approximately in the range of $187 million to $205 million recurring annual costs are estimated at approximately $34 million and investment in engineering controls is expected to be approximately $266 million. Estimates of these costs for various individual industry sectors are analyzed below. As that analysis reveals, the greatest economic impact of the standard falls on the larger and more stable industries, such as petroleum refining and petrochemical production, which can readily absorb the costs or shift them forward to consumers. No testimony was offered by these industries that the proposed standard for benzene would imperil their existence. Even the higher projection of some costs by the American Petroleum Institute and other participants would not raise any serious question concerning the economic feasibility of the standard or the ability of the regulated industries to bear the additional costs.

The benzene standard, in its final form will require all industries that produce or use benzene, petrochemicals, products and services involving the use of solvents derived from petroleum, as well as production of crude and refined petroleum products, and primary distribution of gasoline, to undertake an initial determination of the extent to which their employees are exposed to benzene. The results of the initial exposure measurements will determine the types of activities each firm will be required to take to comply with the provisions of this standard. Where exposure measurements are below the action level (0.5 ppm), firms will have to provide information and training in the hazards related to benzene to their employees, comply with the labelling requirements, and retain the records of initial measurements. These compliance activities account for the entire first year operating costs for many of these industries. Firms with exposure levels above the action level will incur additional first year costs for monitoring and medical examination programs. Finally, those firms with exposure levels above the permissible exposure level will have additional first year costs for installation of appropriate engineering and work practice controls, and for respirators. It is assumed that engineering controls are all installed in the first year and reduce exposure levels to below the permissible exposure limit. However, those firms with continuing exposure measurements above the action level will have recurring annual costs for monitoring and medical surveillance. Regardless of the airborne exposure measurements, employees in operations with potential exposure to eye or repeated skin contact will have to be provided with appropriate personal protective equipment. Thus, some firms and industries will have higher and more sustained cost burdens than others.

OSHA's estimates of costs for compliance with the final standard differ from estimates of the proposal's compliance costs in part because the standard in its final form differs from the proposal in areas which significantly impact on the cost of compliance. ADL estimated the proposal's compliance costs for 20 industry sectors engaged in benzene production (petroleum and coke), petroleum refining, chemical processing, benzene transportation, and other industries, such as rubber manufacturing and laboratories (ADL, Vol. 1, Ch 5). ADL provided detailed cost estimates for each industry and for each compliance activity required by the proposal. Total costs for all surveyed industries were estimated by ADL as follows: First year operating costs were approximately $124 million, recurring annual costs were approximately $74 million, and costs for implementation of engineering controls were approximately $267 million. In developing each of these estimates, ADL used the control with the least cost as the basis of their calculations. In other words, where alternative methods of compliance are available to employers in an industry, and indeed may be more attractive to employers, the higher cost method was considered an optional process improvement, and only that portion of its total cost required to produce compliance was allocated to compliance with the proposed regulation (ADL, Vol 1, pp. 5-3). Additionally, ADL assumed compliance with the previous OSHA regulation (29 CFR 1910.1000, Table Z-2) requiring an exposure limit of 10 ppm TWA and a ceiling limit of 25 ppm, thus assessing to the benzene proposal only the incremental cost associated with

moving into compliance with the proposed permissible exposure level from the previous exposure limit.

The ADL costs covered 24,312 facilities and 196,875 estimated exposed employees (ADL, Ex. 5A, Table 5-1, p. 5-2). Costs were estimated for the required compliance activities of monitoring, medical surveillance, respirators, personal protective equipment, training, signs and labels, and recordkeeping. Distribution of costs varied from sector to sector depending on such variables as the number of exposed workers who would require monitoring and medical surveillance and the estimated effectiveness of engineering and work practice controls. OSHA has examined the methods used by ADL to determine the costs for each provision of the standard and, in the absence of substantially contradictory testimony and alternative methods from affected industries, the approach of ADL has been largely adopted by OSHA in estimating the costs of compliance.

Based on all the evidence on the record, OSHA has estimated the cost of compliance with the benzene permanent standard for approximately 157,000 facilities and approximately 629,000 exposed employees.

Monitoring

As a basis for OSHA's estimates of compliance costs, OSHA has utilized for many industries ADL's sampling protocol for determining monitoring costs. ADL's protocol was designed to provide an initial exposure profile and characteristic sampling program.

ADL's representative explained that the protocol was intended to be representative, but that it might not fit each plant exactly and costs might be higher if the number of exposed workers in an industry, or those exposed above the permissible limit, were higher. (See Tr. 477-484, 522-526, and 592-595.) The derivation of the sampling base further explained in ADL's post-hearing submission as follows:

> The vast majority of facilities which must comply with this regulation are typified by twenty-four hour per day continuous processes representative of petrochemical operations. It was proposed to initially sample 50 percent of all exposed employees. However, the three shift nature of these operations and the commonality between worker exposures by job category between shifts indicated that sampling results from one shift could be properly interpreted as being representative for all shifts. Therefore only ⅓ of the exposed workers should be sampled. Multiplying ½ × ⅓ equals ⅙ of the exposed employees who must be monitored. (Post-Hearing 15E)

OSHA recognizes that these assumptions may not portray exactly the monitoring pattern of employers within other industries. It is OSHA's view, however, that the monitoring scheme as described is a reasonable basis for estimating the cost of compliance with the monitoring requirements of the final standard.

In estimating the percentage of employees within each exposure category—i.e., above the permissible exposure level, between the action level and the permissible exposure limit, and below the action level, OSHA has used varying assumptions based on exposure data, where available. For the major portion of the covered industries, OSHA has accepted ADL's estimate that 20% of the exposed employees are above the permissable exposure limit. While there may be some variations in actual percentages at individual plants, industry witnesses offered no alternative approaches to estimating the number of exposed employees above the permissible exposure limit. Determination of the percentage of employees in each of the two exposure categories below the permissible exposure limit was based to the extent possible on record evidence of exposure. Where such evidence was not available, it was assumed for cost calculation purposes that one-half of the employees were exposed below the action level and one-half were exposed between the action level and the permissible exposure limit. Use of this distribution of exposed workers, however, does not imply that OSHA believes it necessarily represents actual exposure profiles for all industries; it has been used only to provide some basis for estimating approximate compliance costs and assessing the economic impact of the standard on these industries. OSHA has therefore, relied on the best available evidence as to likely exposure patterns in determining that its sampling protocol reflects typical industry conditions, provides a uniform estimation method enabling inter-industry comparisons to be made, and yields reasonable approximations of the cost impact of the monitoring program.

OSHA has utilized the ADL methodology for calculating monitoring costs. There are, however, significant differences in total monitoring costs as a result of changes in the monitoring requirements of the final standard. The elimination of the proposed percentage exemption expands the number of employers covered by the standard and the number of employees affected. Cost estimates for compliance by employers using liquid mixtures containing less than 1% benzene were not given in the ADL study. However, inclusion of an action level in the standard, below which no regular monitoring or medical surveillance is required, should minimize the economic impact of the permanent standard. This is especially true since the proposal would have lowered the percentage exclusion to 0.1% after one year, and would have imposed periodic monitoring and medical surveillance of employees in these operations with any amount of exposure to benzene. Furthermore, it is anticipated that a significant number of operations utilizing mixtures with less than 1% benzene will be below the action level, in which case only initial monitoring must be conducted.

The introduction of an action level decreases for individual employers the cost of compliance for the monitoring activities. The proposal required quarterly monitoring where exposures were at or below 1 ppm. The final standard requires initial measurement to determine exposures but requires no further monitoring where exposures are below 0.5 ppm (unless a redetermination of exposures is necessitated by specific changes). As a result of this change in the monitoring requirements, some employers, who would have been required to monitor employees quarterly, will now only need to conduct initial measurements. Initial measurements it is estimated will cost approximately $109 million for all industries combined. However, the actual cost will be substantially below this, inasmuch as the standard allows employers who have conducted initial monitoring, pursuant to the benzene guidelines or the emergency temporary standard, to utilize those measurements in order to initially determine employee exposure; and the benzene record indicates that many employers have conducted these measurements.

Medical Surveillance

The final standard, unlike the proposal, requires medical surveillance only of those employees whose exposure is at or above the action level. Moreover, the standard provides for twice yearly medical exams rather than quarterly exams. ADL has estimated the annual cost for routine medical surveillance as approximately $207 per employee annually, (Vol. II, App. C). This figure included employer and employee time, physician charges and laboratory fees. (Vol. II, C-7).

Since routine medical surveillance is required by the permanent standard semi-annually rather than quarterly as contemplated by the proposal, OSHA has adjusted the ADL medical cost per employee to reflect the reduction in the number of periodic exams and to remove from the periodic exams the cost of the reticulocyte count and serum bilirubin, which the permanent standard requires only as part of the initial baseline exam. OSHA has, therefore, estimated the cost of the first year medical surveillance, including the work history, as approximately $105.00 per employee and the recurring annual cost of medical surveillance is estimated as approximately $78 per employee.

The final standard provides for medical surveillance in addition to semi-annual routine blood testing. Where routine medical surveillance reveals an abnormal blood picture, the employer is required to refer the employee to a hematologist. Where emergency situations occur, the employer is required to provide a urinary phenol test and, if urinary phenols are elevated, a repeat complete blood count (CBC); if the CBC reveals abnormalities then the employee must be examined by a hematologist. The cost of these non-routine examinations was not estimated by ADL since they would not have been required by the proposal. There is, of course, no certain way of determining the number of employees who will need examination by a hematologist. To calculate these additional costs, therefore, OSHA has assumed that 5% of all employees will have abnormal blood pictures and will be re-referred to a hematologist, and that the added cost will be $100 per referral.

Other Costs

Total costs for other compliance activities, such as engineering controls, respirators, training, and signs and labels have also been assessed. These costs are based essentially on the cost factors furnished by ADL since the ADL costs were generally accepted by industry participants.

Capital costs for engineering controls have been determined for industries with operations above the permissible exposure limit on the basis of the type of engineering controls available for the individual industry. Many of the industries covered by the benzene standard involve the storage and movement within a closed system of liquids containing benzene in various concentrations. Emissions occur at such points as pumps, pipe line joints, compressors, sampling points, and gauging stations. (Vol. 1, 4-35). Engineering controls for these systems consists of replacing worn pumps and compressors with equipment specifically designed to minimize emissions, replacing gaskets to ensure tight fit of joints, welding joints, and the installation of automative gauging and closed loop sampling devices. Specific units of these systems have been costed by ADL and aggregate costs shown below are based on an estimated number of these units which are required for a typical plant. To determine respirator costs, OSHA has used ADL's cost per employee for respirators. (Vol. II C-8, 9). For personal protective equipment, which is required by the standard for employees who may be exposed to eye or repeated dermal contact with benzene, the cost of $13.16 per employee per year has been used. This cost includes the cost of gloves, apron, faceshield, and goggles (Vol. II, C-R). Training costs, which include costs for preparation, materials, employee's time, and instructor's time, have been estimated at $110 per facility plus $14 per employee (Vol. II C-II).

In calculating recordkeeping cost, OSHA has utilized the ADL cost factor (Vol. II C-12) for record maintenance but adjusted this cost to reflect the decrease in the records required by the final standard. In its testimony, AISI expressed the view that recordkeeping would require the addition of one record clerk per facility (Tr. 3165-317 I). However, the final standard significantly reduces the monitoring records and eliminates medical records for employees whose exposure is below the action level. Therefore; application of ADL's cost formula will give a reasonable approximation of the recordkeeping burden.

For most firms, a normal cost for labels has been determined on the basis of ADL's cost of estimate (Vol. II, C-13). No cost has, however, been determined for signs. Detailed data on a plant-by-plant basis were not available to OSHA. Therefore, no costs for this compliance activity are included within the cost estimates shown herein. OSHA recognizes that these costs will occur but is of the opinion that they will be relatively small for all firms covered.

Compliance costs for the following industries have been calculated by OSHA using the compliance factors described above.

Petroleum Refineries

It is estimated that petroleum refineries will incur greater compliance costs than any other industry sector. This is primarily due to the large number of refinery workers who are exposed to petroleum products, almost all of which contain benzene. There are 48 refineries engaged in the production of benzene and 275 refineries which do not produce benzene but maintain process streams with benzene concentrations.

At the 48 refineries which produce benzene, there are approximately 1,440 exposed workers. On the basis of the exposure data made available by ADL and industry witnesses, it appears that approximately 20% of these employees are exposed above the permissible exposure limit. OSHA has, therefore, applied the ADL sampling protocol and calculated costs on the assumption that initial measurement will show approximately 300 workers exposed above the permissible exposure limit. The remaining exposed workers were divided for cost calculation purposes. Capital investment to reduce exposure levels has been estimated at approximately $24 million extrapolating from a model plant analysis. This cost would be for replacement of seals and controls of leaks (ADL, E-1) and similar indicated improved maintenance and repair. No estimate is made for shut down time since it is anticipated that any controls including modifications of pumps and compressors, would be installed during normal down time (Tr. 536). OSHA does not concur in the API view (Scarborough statement p. 36-7) that additional down time is needed since normal maintenance procedures of highly flammable material require purging of lines, and replacement of seals, pumps, etc. First year operating costs for these refineries are estimated at approximately $600,000.

Cost estimates for the 275 refineries which do not produce benzene were based on API's and ADL's data as to 98,000 exposed employees. (ADL, Vol I, p. 419; add API reference for that number). ADL relied in part on the results of an API questionnaire which indicates a wide range of exposures from negligible to as high as 25 ppm. (ADL pp. 4-16 to 4-17). API's witness indicated that exposures at refineries were very low with most below the proposed permissible exposures limit and many below the action level (Tr. 1467-1468). Other testimony indicates similar exposure patterns (Grospiron statement, pp. 4-6). The API post hearing submissions suggest that refinery workers move frequently from one post to another so that they are not exposed to hydrocarbon vapors for extended periods of time (API, PH5). Initial monitoring results showing 8 hour TWA measurements of 0.13 ppm and lower were cited by API. (API PH 8-9.) In the face of conflicting data of this sort, it was assumed that approximately 5,000 workers initially could be found to be exposed above the permissible exposure limit, that approximately 5,000 would be exposed at levels between the permissible exposure limit and the action level, and that the remaining 88,000 would be below the action level. This distribution indicates somewhat higher exposure levels that API's testimony suggests, but lower levels than the results of the API questionnaire survey might be construed to indicate and is, therefore, intended to be a reasonable estimate. Using this distribution, OSHA estimates first year operating cost for compliance to be approximately $12.8 million. It may be noted that approximately $2 million of the indicated first year cost is for exposure measurements. Since many refineries have apparently made such measurements, actual first year compliance costs may be substantially lower than the estimates listed herein.

The cost of capital investment in engineering controls is estimated to be $110 million, for control of leaks from seals and valves, control of sumps and other disposal areas, and control of other emissions associated with stor-

age, transfer, and gauging activities. If it is assumed that application of engineering controls is highly effective in bringing all worker exposures to levels below the action level, recurring annual costs would decline to approximately $3.5 million. If, alternatively, it is assumed that as many as 5,000 refinery workers may continue to be exposed at levels between the action level and the permissible exposure limit, recurring annual costs would be approximately $4.4 million. OSHA believes the latter assumption is indicative of the upper bound of these annual costs.

Coke Plants

Compliance costs related to the production of benzene as a byproduct of coking are associated with activities at the coke batteries and at light oil processing facilities.

There are some 65 affected coke producing facilities. ADL had estimated that there were approximately 17,000 employees potentially exposed to benzene at coke oven batteries. The American Iron and Steel Institute (AISI) challenged this number as being an underestimation of exposed employees. The larger figure of 24,000 workers exposed at the coke oven batteries has been used by OSHA as urged by AISI. (TR 4635, 472-4) This was the number estimated to be exposed to coke oven emissions in the Economic Impact Statement for the Coke Oven Emissions Standard. It is probable that this constitutes an overestimate of workers exposed to benzene at the coke oven batteries since benzene emissions are expected to occur only during portions of the production cycle and not at all locations. (ADL, PC, 15f, 15i).

The AISI number is used, however, to avoid all possible underestimation of compliance costs for coke oven batteries and to indicate an upper bound to the probable costs. On the basis of data supplied (Ex. 135, p. 4 and attachment), it is assumed that initial measurement of exposures will show all workers exposed to benzene concentrations below the action level. Even if this were not the case, OSHA believes that engineering controls required under the coke oven emissions standard would provide adequate control of benzene emissions. On this basis, the estimated compliance costs are approximately $1.2 million for first year operating costs and $860,000 for recurring annual costs. Since employee exposure does not exceed the permissible exposure limit, no capital cost is indicated for compliance with the benzene standard at coke oven batteries.

There are 65 coke oven light oil facilities associated with the coke oven batteries. ADL estimated that 2,370 employees were potentially exposed at the derivative light oil facilities. AISI argued that this number should be 4,000 employees. Consistent with the reasoning followed to estimate the number of workers exposed at coke oven batteries, the number of workers exposed in the light oil byproduct areas has been estimated to be 4,000, the number used in the coke oven emissions study. Data provided by ADL and AISI indicate that a substantial percentage of these workers may be exposed to benzene above 1 ppm. AISI specifically argued that at least 50% of by-products workers are exposed above the permissible exposure limit (AISI brief, p. 95). Consequently, to avoid any possible underestimation of compliance costs and indicate the upper bound of such costs, it has been assumed that all exposed workers will be exposed above the PEL at the time of initial measurement. Using these estimates of exposure, estimated compliance costs are $5.6 million for first year operating costs. OSHA has assumed that, after the installation of engineering controls, all exposures will be between the action level and the permissible exposure level. Since a significant number of light oil plants are old, controls may not result in reduction of exposure to below the action level. AISI expressed the view that engineering controls for older plants might not be feasible (P.I. statement p. 19); however, it appears that this concern was for economic rather than technological reasons. Thus, recurring annual operating costs are estimated at $887,000 for training, labels and recordkeeping. Capital costs are estimated at $19 million for investment in engineering controls.

Petrochemical Industry

The petrochemical industry includes firms producing a large variety of products from petroleum feedstocks. Six petrochemicals, accounting for about 90% of domestic consumption (ADL, Ex. 5B, B-96) were analyzed separately by ADL (Ex. 5A, 6-18ff) but since the exposure patterns of each are similar and the ecomonic impacts affect many of the same or competing markets, the costs of petrochemicals have been aggregated by OSHA. The industry sectors included are chlorobenzene, cumene/phenol, cyclohexane, dodecylbenzene, ethylbenzene/styrene, maleic anhydride, nitrobenzene. This follows the analysis provided by ADL and the cost estimates shown are based on ADL's data. Industry participants did not challenge these costs.

There are 92 facilities covered by this standard, with 2,760 exposed workers. (ADL, Ex. 5A, p. 4-4) On the basis of the limited data available on exposure levels (Vol. 1, pp. 4-7; Table 4-8, pp. 4-12 ff), it was assumed that 40 percent of the exposed workforce is exposed to benzene levels below the action level, 40 percent between the action level and the permissible exposure limit, and 20 percent above the permissible exposure limit. On this basis, first year operating costs will be approximately $1 million. Capital investment for engineering controls will be approximately $20 9. Recurring costs will be approximately $118,000. Recurring costs include training, labels, and recordkeeping since it assumed that engineering controls will reduce exposures below the action level.

Bulk Terminals

Storage and discharge of gasoline, and other petroleum products at bulk terminals is included within the benzene standard.

It is estimated that there are 1,992 terminal facilities with 52,345 exposed workers. Testimony by industry witnesses indicated that by and large, no terminal employees were exposed to benzene levels in excess of 1 ppm (Tr. 1469-70, 1472-73; Ex. 115A,10, pp. 17-19). Using these indicators of possible exposure distributions, OSHA has estimated compliance costs for terminals on the basis of 5,000 workers exposed to benzene between the action level and the permissible exposure limit, exposure with all other workers below the action level. On this basis, first year operating costs would be approximately $5 million and recurring annual costs would be approximately $2 million.

It is estimated that there are 21,106 bulk plants employing 23,471 drivers who are potentially exposed to benzene at terminals (ADL, Ex. 5a). Again using the limited data supplied by API, it was estimated that as many as 2,300 of these workers would be exposed at levels above the action level but below the permissible exposure limit. Conversion to bottom loading on all trucks was projected to reduce all exposures to below the action level. On this basis, first year costs were estimated at approximately $17.9 million, recurring annual costs at $3 million, and capital investment at $51.5 million

Oil and Gas Production

There are approximately 700,000 oil and gas wells in the U.S. and, since any crude oil or natural gas may be expected to contain benzene, all of these are covered by the standard. API indicated that the number of exposed workers is 74,000 and that exposure levels are below the action level (Ex. 115A, 4, Ex. 116). As noted in the section on technological feasibility, workers are normally exposed only intermittently and occasionally, and emissions are limited to points where leaks or spills occur (Galloway, API, Ex. p. 116, pp. 4-5). Proper work practices and good maintenance can minimize

these exposures. It may reasonably be inferred, therefore, that all workers are exposed to benzene levels below the action level. Compliance costs, estimated on the basis of the reasoning used above, are approximately $39.6 million for first year operations and $2.6 million for recurring annual operations.

In determining these compliance costs, OSHA has assumed 10 wells per facility in contrast to API's reference to each well as a separate facility. It is probable that even this computation overestimates first year and recurring annual operating costs, since the costing formula for initial measurments allocates substantial charges on a per facility basis, amounting for example to approximately 90 percent of first year costs. The estimated first year costs would be reduced by the amount appropriate for measurements already performed pursuant to the benzene guidelines or the ETS. Monitoring costs would further be reduced where exposures at one workplace are representative of exposures at another.

Transportation

Companies engaged in the transportation of benzene and benzene contaminated products are covered by the benzene standard. OSHA's costs analysis, therefore, covers the transportation by pipeline, marine tanker, barge, tank car and tank truck of benzene and benzene products.

The cost analysis for pipelines is based on approximately 3,000 facilities. This figure was furnished by an API witness (Scarborough) who testified that there were 3,000 pipeline facilities employing 12,000 exposed workers. A witness for Williams Pipe Line Company estimated that there are 17,000 exposed pipeline workers (Bailey). The Williams figures, however, may represent total employment, including administrative and clerical workers. OSHA has utilized the figure of 3,000 facilities in combination with the two estimates of exposed workers to yield a range of estimated compliance costs. On this basis first year operating costs are estimated to be approximately $2.7 million and recurring annual costs for personal protective equipment, training and recordkeeping approximately $800,000. Since the standard does not require labelling of pipelines, no labelling cost is included. Neither have engineering controls been assessed since industry measurements indicate that all workers will be below the action levels (Bailey).

The number of affected tank car facilities (loading and unloading) was estimated by ADL to be approximately 100, with an average of one exposed worker per facility. (Table 5-1) The exposures of these workers will be dependent on the quantity of the various benzene-containing products shipped through the facility, the methods of loading and unloading cars, and the effectiveness of efforts to avoid leaks and spills. Conditions are somewhat similar to other facilities at which benzene and benzene-containing liquids are stored and transferred. Following the sampling protocol used throughout this analysis, costs were assigned on the basis that 20 percent of the exposures are above the permissible exposure limit, 40 percent between the permissible exposure limit and the action level, and 40 percent below the action level. It should be noted that, since it was estimated that only one worker per facility would be exposed, monitoring cost were estimated on the basis of 100 employees monitored. Engineering controls are to be installed at these facilities that will effectively control benzene emissions, bringing the exposure levels of all exposed workers below the action level. On the basis of this reasoning, it was estimated that compliance costs will be approximately $215,000 for first year operations, $16,000 for recurring annual costs, and $200,000 for capital investment.

Analysis of tank truck facilities shows a pattern very similar to that for tank cars. The rationale just described yield the following estimates: 200 affected facilities, 200 exposed workers, first year operating costs approximately $428,000, recurring annual costs approximately $37,000 and capital investment $100,000.

Barges are used for the transportation of benzene from refineries to points of utilization. Barges also transport various refined petroleum products primarily for discharge at bulk terminals. It is estimated that there are 480 employees and 240 barge facilities involved in the transportation of benzene. The record indicates that employee exposure during loading and unloading exceeds the permissible exposure limit (Ex. 5A, 4-24). For cost calculation purposes, OSHA has estimated that 20% of the employees are above the permissible exposure limit, forty percent are between the action level and the permissible exposure limit, and forty percent are below the action level. On this basis first year operating costs are calculated at $526,000, recurring annual costs are calculated at $95,000 and capital investment is estimated to be $420,000.

Barges and marine tankers are also used for the transportation of gasoline. The distribution of these exposures, however, appear to resemble those encountered during gasoline production and distribution. In that case, the average cost of compliance per employee in his transportation, loading and unloading operations would range from $100 to $750 per employee.

Laboratories

Benzene exposures occur in chemical laboratories where benzene and other petroleum-based solvents are used. Where careful laboratory procedures are followed, such as the use of properly functioning hoods and appropriate work practices, exposures should be very low. In order to estimate the range of possible costs, OSHA calculated the cost on the basis of two scenarios. One scenario assumes that 10 percent of the exposed workers are initially exposed above the action level but below the permissible exposure level. The second scenario assumes 5 percent of the exposed workers are initially exposed above the permissible exposure level, 10 percent are exposed between the action level and the permissible exposure level, and all others are below the action level. On this basis, first year operating costs range from approximately $4.5 million to $10.9 million. Recurring annual costs would be approximately $2.4 million, if all workers exposures drop below the action level after the first year, which is expected as a result of appropriate controls and work practices.

Rubber Products

The ADL study examined the potential for benzene exposure in plants manufacturing rubber tires and other products, such as belts, hoses, fittings, and coated fabrics. ADL identified 206 affected tire producing facilities employing 11,400 exposed workers. The study cited data indicating that exposure levels were generally in the range of 1-3 ppm and may be considerably higher (ADL, Ex. 5A, pp. 14-19; Tr. 4-20). Similar testimony was provided by Drs. Tyroler and Harris of the University of North Carolina based on their studies of benzene exposure in the rubber industry. (Tr. 3083-3095) Both studies indicated that control of exposure could be achieved, reducing exposure levels to below the action level, by substitution of materials and enforcement of appropriate work practices, and that engineering controls would not be required. (Tyroler, Tr. 3086) Compliance costs were estimated, therefore, on the basis of all exposed workers being exposed initially above the permissible exposure limit, and exposures reduced to below the action level after controls have been instituted in tire manufacturing plants.

First year operating costs were estimated to be approximately $15.8 million and recurring annual costs approximately $407,000.

The analysis of firms producing other rubber products was based on the same considerations of workers exposed and compliance activities. For these firms first year operating costs were calculated at approximately $18.1 million, and recurring annual costs at approximately $484,000 based on 197 facilities with 13,050 exposed workers.

Other Industries

There are a number of other industries in which benzene exposures will occur due to the use of solvents, containing benzene in the processes or products involved. OSHA has estimated the approximate level of anticipated compliance costs for 16 industries thought to be representative of the range of cost impact involved: Adhesives manufacture and application, paint manufacture and application, paint stripper manufacture and application, printing ink manufacture, and gravure printing, metal can production, manufacture of photographic equipment and supplies, production of motors and generators, commercial printing manufacture of folding paperboard boxes, paper mills, and manufacture of wood household furniture. Firms in these industries are relatively small, use similar materials, will have generally low exposure levels, and can effect control of all worker exposures to below the action level by substitution of materials and enforcement of good work practices. It is OSHA's judgment that most of the employees in these industries are exposed to benzene levels below the action level. However, some data in the record on employee exposures related to the use of these solvents indicate that some workers in particular industries may be exposed at higher levels. OSHA feels that the probable range of costs can be indicated by calculating the costs under two hypothetical exposure patterns: (1) If 10 percent of the exposed workers are exposed above the action level, but below the permissible exposure limit, and all other employees are exposed below the action level; and, (2) if 5 percent of the workers are exposed above the permissible exposure limit, 10 percent between the action level and the permissible exposure limit, and all others below the action level. Costs calculated in this way indicate that, in these industries, the first year operating costs will lie in the range of $2,000 to $3,270 per facility, or $240 to $390 per exposed worker.

OSHA is aware that there are other industries where employee exposure to benzene may occur. However, although an opportunity to present data and views as to the application of the benzene standard to all industry sectors was afforded, no submissions were made on behalf of these industries. In the absence of exposure and cost data, OSHA has been unable to calculate costs for those industries. In summary, OSHA finds that the economic impact of the final benzene standard will not be such as to threaten the financial welfare of the affected firms or the general economy.

Other Economic Impacts

In addition to assessing the compliance cost and economic feasibility of the proposed standard, OSHA evaluated the economic impact of the proposed standard on affected industries and the general economy utilizing the criteria of Executive Order 11821 (39 FR 41501) as amended by Executive Order 11949 (42 FR 1017), and related implementing instructions particularly Secretary's Order 15-75 (40 FR 54484). The evaluation of such impact was made a part of the economic analysis of ADL. The methods of evaluating these impacts and the conclusions reached were extensively discussed during the benzene hearing.

The portion of the ADL study was designed to show the economic effects of compliance with the proposed final benzene standard upon affected industries. OSHA believes that this analysis, as modified to reflect the changes made in specific provisions in drafting the final standard, adequately defines the economic impact of the final standard.

ADL's analysis was, as discussed further below, challenged by witnesses for AISI and API on the ground that it was not sufficiently rigorous. Neither AISI nor API questioning of the ADL costing methodology indicated serious disagreement with the data used. Nor did these witnesses offer any evidence tending to disapprove the conclusions reached by ADL, or suggest specific analytical procedures which, if followed, would clearly improve the study and increase the accuracy of the findings. After careful consideration of each of the questions raised by these and other witnesses, OSHA has made minor modifications in some elements of the cost analysis, and has concluded that the evidence indicates that the economic impact of the final standard may be more widespread than that shown in the ADL study but less severe for the industries analyzed by ADL.

Impact on Energy, Critical Materials, and Other Macroeconomic Variables

The ADL analysis indicated that there would be no significant change in either the supply or demand sides of the markets for energy or critical materials.

Two economists testifying for API argued that these were important areas of potential impact improperly ignored by ADL. Scarbrough, p. 4-5 and Henderson, p. 6-7). Under questioning at the hearings, however, neither witness offered any data indicating that these effects would be significant or put forth any reasons to suggest that they would be. (Tr. 2225-2226, Scarbrough, and Tr. 2212-2214, Henderson.)

Impacts on Prices

The compliance costs identified in the cost analysis provided the basis for estimating the impact on prices, output and labor productivity. The indirect costs resulting from increases in the prices of benzene and products made from it were identified and included in the estimation of impacts on producers and consumers. Capital costs were amortized over 7 years at 10 percent to reflect a normal return on investment. ADL assumed that the price would increase in the long run by the amount of any increase in long run average cost, including the normal return to investment. This provides a reasonable approximation of maximum potential price impact, and OSHA considers it to be acceptable where exact costs cannot be known and precise measurement of price changes is not feasible.

Impact of Prices on Output and Market Structure

Economic impact was judged on the basis of expected overall influence of price increases, product substitution, price elasticity of demand, market growth, volume of imports and exports, market concentration, and compliance cost differentials.

ADL reasoned that buyers of benzene will continue to purchase the same quantities after a small price increase, provided there are no economical substitutes for benzene and provided that they can pass the added cost along in the price of their products. If users of the end products reduce their purchases in response to the cost pass-through, then the industrial purchasers will change the mix of products they manufacture and buy less benzene. The elasticity of consumer demand in turn depends on whether consumers can substitute other goods of the same type for those whose prices increase as a result of the cost pass-through, and whether consumers reallocate their incomes to buy other kinds of goods and services while buying less of the ones whose prices increased.

The magnitude of the expected costs is such that the percentage change in consumer product prices would be very small. No income effect (reallocation of income) of any significance would be expected. Therefore, elasticity would reflect almost entirely the availability of substitutes, as ADL indicated, although this conclusion would be questionable if a large price change was anticipated. ADL's product-by-product discussion of the availability of substitutes for benzene and for the petrochemical products made from benzene showed clearly that in all major product lines substitutes were judged to be technically inferior and more costly, at best, and unavailable with present technology in may instances. (ADL, Ex. 5A, pp. 6-18 to 6-22.) Consumer substitution was also judged to be sharply limited on the

basis of the quality and cost of available substitutes. OSHA believes that the reasoning followed by ADL in this qualitative analysis is reasonable.

Using an estimate of relatively inelastic demand for benzene (elasticity = −0.5) (ADL pp. 6–11) and an estimated price increase of approximately 1 percent, ADL estimated that demand for benzene would fall by approximately 0.2 percent (16 million pounds) in the short run and by approximately 0.5 percent (54 million pounds) in the long run for refineries and steel companies producing benzene. Since the demand for benzene is growing moderately, these decreases would represent a slight decrease in the amount of growth, rather than an absolute decline from current levels of production. Foreign trade accounts for only 5 percent of U.S. supply and is not expected to be a significant factor affecting domestic producers, considering the small projected change in price.

The price of benzene is determined by petroleum refiners, who supply 95 percent of the market. Since coke oven producers will incur higher compliance costs than the benzene producing refineries, they will be able to recover only part of their costs through price increases and will be adversely affected by the standard. It appears probable that some producers of benzene from coking operations will choose to sell their light oil to other firms rather than continuing to produce benzene (AISI). Similarly, some refineries now producing benzene may elect to change their product mix to eliminate benzene production. These decisions will be made by benzene producers on the basis of many factors affecting the profitability of benzene production and not on the basis of the impact of this standard alone.

No data were submitted in the hearings that provided a basis for estimating the number of firms that may eliminate benzene production. It was not contended, however, that any producing firm will be forced to close or be forced into an unprofitable position as a result of the compliance costs associated with this standard.

Impact of Price on Employment and Productivity

Since ADL projected no absolute decrease in total production of benzene, it did not project employment losses for benzene producers. API witnesses questioned this on the basis of their challenge of the analysis of demand elasticity, price change, and reduction of demand. (Scarbrough, pp. 24–25; Henderson) OSHA reasons, however, that if these elements of the analysis are acceptable, the conclusion that production employment will not decline is valid, although some reallocation due to structural changes in the industries may occur.

API also argued that increased labor cost resulting from compliance programs could lead to some substitution of capital for labor. (Henderson, p. 10) In its testimony, ADL pointed out that the productivity of both labor and capital would decline in the same order of magnitude and that this would indicate that substitution would not occur. (TR p. 584) ADL also submitted that the industry sectors in question are quite capital intensive and that for this reason, "it is not anticipated that the proposed regulation would have any observed effect upon the utilization rate for labor in these industries." (ADL post hearing, Ex. 15N)

OSHA recognizes that some decline in overall labor productivity may result from adding compliance personnel such as technicians and hygienists to the work force of benzene producers, although the direct productivity of production workers is not affected. This decline was estimated by ADL to be approximately 1.4 percent for coke producers and 0.6 percent for refineries (ADL, Ex. 5A, Table 6.5, p. 6–16).

Benefits

The legislative history and language of the Occupational Safety and Health Act, as distinguished from some other environmental and safety legislation, clearly indicate that Congress has already arrived at a judgment concerning the balancing of cost and benefit, with the result that worker safety and health are to be heavily favored over the economic burdens of compliance. Specifically, Section 6(b)(5) of the Act provides that

> the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection. shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Thus, while feasibility is an appropriate consideration, the Secretary is directed to set standards which attain the "highest degree of health and safety protection for the employee * * *."

This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques. In considering the issue of feasibility in this rulemaking, as in others, OSHA has carefully evaluated the cost of compliance which may be incurred by the directly affected employers and their ability to comply. Additionally, OSHA believes that a standard for a substance which has been found to pose a cancer risk to workers, in this case benzene, must assure maximum benefit (i.e., prevention of serious illness or death), constrained only by the limits of feasibility.

There is general agreement that benzene exposure cases leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on "the frontiers of scientific knowledge." While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a "threshold" or "safe" level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established. In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by prudence and by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

Various witnesses argue that cost benefit or cost effectiveness should be the primary criterion for regulatory decision. OSHA was criticized by industry participants for failure to consider what benefits would be derived from reducing the current permissible exposure level for benzene (API brief, page 92, 96; AISI brief, page 89, 97). The Council on Wage and Price Stability (CWPS) also suggested that OSHA estimate the incremental reduction in health risks which are associated with the reduction in employee exposure to benzene (Bosworth letter, 9/12/77, to Bingham).

Both CWPS and industry suggested ways in which this could be achieved. CWPS suggested that OSHA apply the expected lifetime incidence rates of leukemia and the increased incidence rates revealed by the scientific studies to the benzene exposed population to derive the number of expected

excess cases attributable to that exposure. An MCA witness, Dr. Wilson, assumed a dose response relationship and calculated that at the current exposure levels only one leukemia and one other cancer would be observed among the benzene exposed workers covered by the proposal every 6 years (Ex. 149-B). This witness further testified that the proposed standard would cost $300 million for every hypothetical life saved (Tr 2750) and concluded as a result that the risk from benzene related deaths is comparable to many other socially acceptable risks.

An API witness contended that rational allocation of OSHA's resources required policies that utilize cost effectiveness as the primary basis for regulatory decisions. He further argued that OSHA should make an assessment of what risks exist from exposure to benzene at 1-10 ppm., which should then be compared with estimates of risks posed by other health hazards such as from cotton dust (Tr. 2157) as well as with the risk associated with other activities of society which he termed generally acceptable risks in order to determine whether the cost of the benzene standard is warranted.

In the face of the record evidence of numerous actual deaths attributable to benzene-induced leukemia and other fatal blood diseases, OSHA is unwilling to rely on the hypothesis that at most two cancers every six years would be prevented by the proposed standard. By way of example, the Infante study disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period. While the Infante study involved higher exposures than those currently encountered, the incidence rates found by Infante, together with the numerous other cases reported in the literature of benzene leukemia and other fatal blood diseases, make it difficult for OSHA to rely on the Wilson hypothesis to assure the statutorily mandated protection of employees. In any event, due to the fact that there is no safe level of exposure to benzene and that it is impossible to precisely quantify the anticipated benefits, OSHA must select the level of exposure which is most protective of exposed employees.

We recognize that in view of the latency period usually associated with the induction of cancer, significant reductions in mortality may not be seen for many years. However, unless exposures are reduced now, OSHA believes that the mortality rate will not decline and employees exposed to benzene will continue to suffer excess mortality. Finally, it should be noted that this standard for employee exposure to benzene cannot be simply described as a reduction in permissible exposure from 10 ppm. to 1 ppm. as a daily average. The previous standard for worker exposure to benzene permitted daily exposures as high as 50 ppm. for a period up to 10 minutes and repeated exposures of 25 ppm., levels which are known to produce serious hazards of blood diseases.

In making judgments about specific hazards, OSHA is given discretion which is essentially legislative in nature. However, in setting an exposure limit for a substance like benzene, OSHA may not substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function. Where the health effectiveness of the alternative approaches are extremely uncertain and likely to vary from situation to situation, OSHA must adopt the compliance strategy which provides the greatest certainty of worker protection even if that approach carries with it greater economic burdens for the affected employers. In the case of the benzene standard, the evidence in the record indicates that the costs of compliance are not overly burdensome to industry. Having determined that the benefits of the proposed standard are likely to be appreciable, OSHA is not obligated to carry out further exercises toward more precise calculations of benefit which would not significantly clarify the ultimate decision. Previous attempts to quantify benefits as an aid to decision making in setting health standards have not proved fruitful (41 FR 46742).

Based upon the foregoing and the record as a whole, OSHA finds that compliance with the standard (even if the higher cost estimates suggested by some participants are used) is well within the financial capability of the covered industries. Moreover, although the benefits of the standard cannot rationally be quantified in dollars, OSHA has given careful consideration to the question of whether these substantial costs are justified in light of the hazards of exposure to benzene. OSHA concludes that these costs are necessary in order to effectuate the statutory purpose of the Act and to adequately protect employees from the hazards of exposure to benzene.

VI. Summary and Explanation of the Standard

The following sections discuss the various issues raised during the benzene rulemaking proceedings, the individual requirements of the permanent benzene standard and the rationale and policy considerations underlying the provisions of the standard. In developing these requirements, OSHA has considered all the evidence in the benzene record. After consideration of all of this evidence, OSHA has revised and clarified, as described in detail below, certain provisions of its proposed benzene standard.[1]

Scope and Application: paragraph (a) This standard applies to occupational exposure to benzene in all workplaces in all industries where benzene is produced, reacted, released, packaged, transported, handled or otherwise occupationally used, except for the agriculture industry. Thus, the standard applies to "general industry" as well as to the construction and maritime industries. By specific exclusion discussed in detail below, the standard does not apply to the sale, discharge, storage, transportation, distribution or use as a fuel of gasoline and other fuels, subsequent to discharge from bulk terminals. The application of the standard is further limited in that not all of the requirements of the standard will apply to every employer regardless of the conditions in his workplace. The permanent standard, unlike the emergency temporary standard and the proposed standard, incorporates an action level so that the specific provisions of the permanent standard that apply to any particular workplace depend upon the extent of employee exposure to benzene. Additionally, only the labeling requirements of paragraph (k) (2), (3), (4), and (5) and the training requirements of paragraph (j) apply to workplaces where the only benzene is contained in sealed intact containers.

The scope of the final standard has been significantly changed from the scope of the proposal and the emergency temporary standard. OSHA was faced with several alternatives in deciding on the extent of coverage of the benzene permanent standard and in achieving its objective of maximizing the protection afforded employees occupationally exposed to benzene while limiting the burden placed on their employers. Benzene, as pointed out earlier, is used in a vast number of operations in quantities varying from trace amounts in solvents to large amounts of pure benzene. Coverage of all workplaces where benzene is present would, of course, extend the protection of the standard to the greatest number of employees. It would mean, however, that workplaces where benzene is present only in trace amounts and potential employee exposure is minimal would be subject to the same exposure monitoring and medical surveillance requirements as workplaces where the potential for high employee exposures exists. While this would satisfy that part of OSHA's objective of maximizing the protection afforded employees, it would fail to reasonably limit the burden placed on employers.

[1] For the convenience of the public, OSHA has included, as part of the title of each section of the summary and explanation of the standard, the particular paragraph of the standard to which the discussion refers.

Proposed Percentage Exclusion

The proposal and the emergency temporary standard both would have exempted from coverage those operations utilizing liquid mixtures containing 1 percent or less benzene by volume. The proposal would have limited this 1 percent exemption to the first year of the standard after which period only liquids containing 0.1 percent or less benzene by volume would be exempted. The proposed percentage exemption was based on some indication that exposures resulting from the use of mixtures containing less than 1 percent benzene would generally be less than 1 ppm (42 FR 27453-4). It was also anticipated that the percentage exclusion would lead to a reduction of the benzene content in solvents or to substitution of other substances for benzene with the result that employee exposure to benzene would be reduced or eliminated. As a result of evidence developed during the benzene rulemaking, however, OSHA has determined that the percent exclusion cannot be supported on this basis. The benzene record indicates that there is no consistent predictable relationship between the percent of benzene in a liquid mixture and the resultant airborne exposure to benzene (Tr. 3120). Studies conducted by the University of North Carolina demonstrated that exposure levels varied considerably during various work operations utilizing liquid mixtures containing the same percent of benzene (Tr. 3090-3091). Support for the conclusion that a less than one percent benzene solution can result in exposures above 1 ppm is found in testimony suggesting that other factors than the percent of benzene in the liquid may be determinative of exposure levels. Thus, NIOSH testified that employees working with No. 6 fuel which contains only 0.1 percent benzene were exposed to levels as high as 60 ppm under certain conditions of confined space, poor ventilation or elevated temperatures (Tr. 754). The University of North Carolina data also revealed that exposure levels in heavy duty tire spraying utilizing rubber solvents were 1.3 ppm when sprayed by the regular full time operator but reached 5.2 ppm and 7.3 ppm when sprayed by a substitute operator (Tr. 3093). This suggests that work practices are also determinative of exposure levels. To maximize protection of employees, it is necessary to reduce their exposure to benzene, to the lowest feasible limit. Since the percentage of benzene in a liquid is not in itself necessarily controlling of the employee's exposure level, the proposed percentage exemption, would not achieve this objective. Accordingly, the final standard does not contain a percentage exemption and thus applies to all liquid mixtures containing benzene regardless of the percent of benzene.

It is OSHA's view that the absence of a percentage exemption does not eliminate all incentive to reduce the amount of benzene in liquid mixtures. Where another substance is totally substituted for benzene, this standard will obviously not apply. Additionally, it should be noted that the inclusion of an action level will effectively limit the burden of this standard where employee exposure is found to be low because of its limited presence in a mixture.

Benzene Substitutes

In lieu of the percentage exception, OSHA considered the option of exempting from the standard certain benzene substitutes, such as toluene and xylene (although they may contain small amounts of benzene). An exemption of this type would encourage employers to discontinue the use of benzene and utilize a substitute in order to avoid the requirements imposed by the benzene standard. These substances themselves, however, do contain varying amounts of benzene and, as stated above, there is no evidence of a consistent direct predictable correlation between the amount of benzene and exposure levels. Thus, it was concluded that toluene and xylene, to the extent they contain benzene and result in benzene exposure, would be covered by the standard.

Action Level

OSHA recognizes that the lack of a percentage exemption substantially expands the coverage of the benzene standard to operations which may otherwise have been exempt. In many of these operations, exposure levels below the permissible exposure limit have already been achieved. To minimize the impact of the standard on those employers who have attained these low exposure levels, the final standard provides for an action level. This action level is a benzene exposure equal to one-half of the permissible exposure limit above which certain precautionary measures, such as periodic monitoring and medical surveillance programs must be conducted and below which only a very limited number of the standard's requirements will apply. Thus employees who have an initial exposure measurement below the 0.5 ppm TWA action level will not have to be monitored periodically. If the initial monitoring exposure measurement is below the action level, no further monitoring is necessary until such time as a redetermination may be required as a result of a process, control or personnel change. Furthermore, medical surveillance of individual employees whose initial exposure measurements are below the action level would not be required. Nor would regulated areas need to be established or engineering or work practices instituted or respirators provided. All other provisions of the standard, however, would apply and the employer would need to train his employees in the hazards of benzene exposure, to properly label his products and to maintain the record of the initial exposure measurement and, if any, the record of the redetermination measurement.

The adoption of an action level had been recommended by several participants to the rulemaking. NIOSH, recommended that an action level for periodic monitoring and routine periodic medical exams be incorporated for the purpose of assuring that no employee is exposed above the permissible exposure limit (Tr. 749-750). Industry participants advocated a level which would trigger the periodic monitoring of employee exposure (Com. 24; Com. 72; P.C. 36 AISI brief p. 74, FT. no. 168). A need for an action level is also suggested by the record evidence that some minimal exposure to benzene occurs naturally from animal and plant matter (Tr. 749-750; 759-760). Naturally occurring benzene concentrations, it appears, may range from 0.02 to 15 parts per billion (Ex. 117, p. 1). Additionally, it was suggested by certain employers that their operations be exempted from the requirements of the standard because those operations involve only intermittent and low level exposures to benzene. The use of the action level concept should accommodate these concerns in all cases where exposures are indeed extremely low since it substantially reduces the monitoring of employees who are below the action level and removes for these employees the requirement for medical surveillance. At the same time, employees with significant overexposure are afforded the full protection of the standard.

In developing this regulatory approach to occupational exposure from benzene, OSHA considered the request of those participants to the rulemaking who pressed for exemption from the benzene standard of their particular operations.

Bulk Terminals

The final standards apply to bulk terminal operators but exclude exposure from gasoline, motor fuels and other fuels subsequent to the discharge from the bulk terminal.

During the rulemaking, bulk terminal employers requested that their gasoline operations be exempted from the benzene standard. Bulk terminals are the primary distribution facilities in the gasoline marketing network. A bulk terminal is the first distribution point of gasoline after the gasoline is processed by the refinery. Gasoline

products are transferred from refinery storage to the terminal by pipeline, tanker or barge (Comeaux statement. p. 11; A.D. Little, vol. II, D-35) and placed in larger storage tanks (Tr. 2353) at the terminal. Further distribution from the terminal is most commonly by tank trucks (Comeaux statement p. 11). The gasoline is pumped from the terminal storage tanks into the trucks and distributed directly to consumers, to retail outlets, i.e. retail service stations, or to other secondary distribution points. These secondary distribution points are smaller terminals (Tr. 476) referred to as bulk plants, which also distribute the gasoline by truck to ultimate consumers, such as farmers and small businesses, or to retail outlets. Final distribution of gasoline to retail service stations and to ultimate consumers is, therefore, by truck and either from a bulk terminal or a bulk plant (Comeaux statement. p. 11). Gasoline emissions occur at the storage tanks, at the tank trucks, and from leaks and spills, with the major emissions occurring when tank trucks are being loaded with the gasoline. The majority of terminal storage tanks are equipped with floating roofs which are effective in reducing storage emissions. Some tank trucks have bottom loading which reduces emissions during loading (Tr. 1294).

Participants in the benzene rulemaking argue that the exclusion of gasoline storage and distribution activities subsequent to discharge from the terminals results in an artificial distinction between bulk plants, which are not covered by the standard, and bulk terminals which are covered. (API P.C. 33, pp. 138-140; Comeaux, p. 12 Sexton p. 22). In support of this contention, industry furnished evidence that exposures at bulk plants were similar to exposures at bulk terminals (Ex. 115A-10; Sexton, p. 18; L.C. 4) and that bulk plants handle the same products, utilize similar handling procedures and use basically the same equipment as bulk terminals. From the technological standpoint, it also appears that several of the same types of vapor recovery systems can be utilized by both the bulk plants and the bulk terminals (Tr. 236). The major difference between bulk terminals and bulk plants, it was said, is a difference in the number of gallons of gasoline distributed (Sexton; Durham L.C. 4).

Although this description of bulk terminals and bulk plants suggests that there may exist some basis for treating bulk plants in a like manner to terminals, it does not necessarily follow that bulk terminals should be excluded from the standard. The question of what regulatory action should be taken with regard to bulk plants was, by specific notice issued prior to the benzene hearing (42 FR 32363), not an issue at the benzene hearing. This exclusion of post terminal gasoline marketing activities from the benzene rulemaking was not based on the absence of any hazard. Rather, as stated in its FEDERAL REGISTER notice, OSHA concluded that regulatory efforts to reduce workers' exposure to benzene released during the transportation, storage, distribution and sale of gasoline subsequent to discharge from bulk terminals should await the conclusion of the deliberations of the inter-agency (OSHA-EPA-NIOSH) task force which was actively considering those activities. (As pointed out in the preamble to the proposed benzene standard (42 FR 27453) certain phases of the downstream gasoline activities which have been exempted from the standard, involve additional hazards which may necessitate different protective requirements and the development of appropriate equipment control devices, and require that these downstream operations be handled in an integrated manner.) In the same notice excluding bulk plants as an issue at the benzene hearing, OSHA solicited data and comments regarding those distribution activities "in order to assist in the subsequent development of a proposal for this industrial segment." Therefore, OSHA has presently under consideration the question of what types of regulatory action to propose for the protection of bulk plant employees exposed to benzene. Pending this regulatory action, bulk plants and other post terminal operations will continue to be subject to the requirements of 29 CFR 1910.1000 and to meet the exposure limits of Table Z-2 of that section.

The exclusion of bulk plants from the notice of the benzene rulemaking precludes regulation of those facilities in this final benzene standard. Exemption of the bulk terminals which were covered by the notice of rulemaking, however, would remove from the protection of this standard those employees who are involved in terminal activities. Data from eleven companies indicate that they operate 892 bulk terminals employing 9,900 employees (Comeaux, p. 12). One company alone estimated that over four thousand of its employees were exposed to benzene in its gasoline marketing operations covered by the standard (Sexton p. 20-1). This same company indicated that most of its 924 commissioned agents and 1,014 jobbers handling its products alone would have employees exposed to benzene emissions during terminal activities. It is OSHA's view that benzene's carcinogenicity requires extending the protection of the standard to the greatest number of employees. Accordingly, OSHA deems it necessary to apply this benzene standard to gasoline storage and distribution operations at bulk terminals.

It is OSHA's view that application of the benzene standard to bulk terminal activities will not impose a great burden on bulk terminal employers. The record evidence indicates that the exposures at storage tanks and loading docks at the terminals, of at least some employers range between 0.2 and .41 ppm on an 8-hour TWA (Sexton Ex. 115-A. 10). These ranges are based on measurements taken during the loading of trucks with and without bottom loading equipment. Where employee exposure to benzene is below the action level, as in the case of the range of measurements cited above, the standard imposes a minimum burden upon the employer.

NON-GASOLINE PETROLEUM PRODUCTS AND ACTIVITIES

Industry participants further argued that exemption of downstream gasoline marketing operations discriminates against the non-gasoline phases of the petroleum industry, such as oil and gas production, pipelines, marine petroleum transportation, refineries and petrochemical facilities, because worker exposures and compliance costs are comparable (API PC 33, pp. 140 ff, Com. 29). Crude oil and natural gas producers further argued for exemption of their facilities because conditions at their facilities—namely, open air workplaces, widely scattered employees, the transient nature of their workforce and essentially no exposure to benzene, made compliance burdensome (Com. 33). As stated above, the need to protect the many workers involved in the non-gasoline activities necessitates the inclusion of these activities in the benzene standard. Furthermore, by virtue of the action level concept, these very factors cited by the oil and gas producers will substantially mitigate the burden of the permanent standard on employers.

Air transport participants using aviation fuels, such as kero jet, argued that non-gasoline aviation fuels be included in the gasoline aviation marketing exemption. OSHA agrees. OSHA recognized, in its preamble to the proposed benzene standard (42 FR 27453), the special need to coordinate the Federal Government's efforts in reducing benzene exposure in certain aspects of the distribution of gasoline and other motor fuels. The joint OSHA-EPA-NIOSH task force, consequently, has under consideration the matter of non-gasoline motor fuels. Besides kero jet, there are other types of motor fuels, such as diesel fuels, which raise the same issues of control as gasoline. There may be other motor fuels containing benzene on which OSHA does not have data. OSHA is conducting its own review of gasoline and has solicited information from the public on gasoline (42 FR 32263). It is, therefore, OSHA's intention to determine the

regulatory action to be taken on non-gasoline motor fuels after review of the data and recommendations of the joint Federal task force and evaluation of the information furnished in response to OSHA's notice on gasoline. For these reasons, OSHA has exempted from the permanent benzene standard the storage, transportation, distribution, dispensing, sale or use as a fuel of all fuels (including gasoline, jet fuel, and diesel fuel) subsequent to their discharge from bulk terminals.

Closed Systems

Some participants requested exemption from the standard for workplaces where benzene is present solely in closed systems. The record evidence, however, indicates that closed systems frequently develop leaks, and that it is the amount of the solvent exposed to air (Tr. 3111-3) which, among other variables, is a major determinant in the degree of exposure. Accordingly, OSHA has retained coverage of closed systems in the final benzene standard. However, in the absence of leaks, exposures from closed systems should be below the action level and the impact of the standard in such operations should be minimal.

Laboratories

Still another segment of industry requested an exemption from the benzene standard. Many comments requested that research facilities in both industrial and academic laboratories be exempted from the benzene standard (Com. Nos. 14, 20, 57, 62, L.C. 12, L.C. 13) particularly where the permissible exposure limit is not exceeded (Com. 56, 58). Some comments suggested that separate requirements be developed for laboratory use of benzene (L.C. 12, L.C. 13). These requirements could include mandatory use of hoods (L.C. 9, Com. 21) of a specified velocity (L.C. 8, Com. 18) and periodic medical surveillance (Com. 18, 28, 29, 64, 70); annual inspection in lieu of monitoring (Com. 28); written safety rules (Com. 18) and container labeling (Com. 39) were also suggested. In the alternative, it was suggested, OSHA should promulgate separate regulations for all chemicals used in laboratories (L.C. 12, L.C. 13), since laboratories use a variety of chemicals, and compliance with separate regulations for each chemical, it was argued, would be burdensome (Com. 58).

The requests for exemption from the benzene standard or for special treatment of laboratories were largely based on the view that there exists a lesser, or slight, risk of exposure to benzene for laboratory technicians. In support of this contention, laboratories pointed to the manner in which they use benzene. Laboratories, it was stated, generally use small quantities of benzene at a time (Com. 10, 28, 38). One laboratory reported that sometimes a sample is dissolved in only one ml of benzene (L.C. 2). That laboratory estimated that an individual laboratory technician, who analyzed 25 samples per day, 7 days a week, would use less than four gallons of benzene a year (L.C. 2). When not in use, benzene is stored in closed containers (L.C. 1).

The argument that laboratory technicians are trained in the hazards of chemicals was also made to support the view of lesser risk. One laboratory reported that it conducted blood tests every four months for twenty years of its technicians, and found no problem (Com. 4). Another reported that in thirty-five years, none of its employees developed leukemia even though exposures in the laboratory were between 1 and 20 ppm (Com. 31).

Another reason advanced for exemption or separate treatment of laboratories was the burden and cost of implementing exposure monitoring, engineering controls and medical surveillance (Com. 4, 5, 10). One industry comment argued that responsible research and quality control laboratories normally provide and encourage annual physical examinations that include the essentials of the proposed medical surveillance program (Com. 38).

OSHA has determined that applying the provisions of this benzene standard to laboratories is consistent with OSHA's responsibility to protect the health and safety of workers. The record indicates that exposure levels in laboratories vary greatly. While monitoring samples of one laboratory indicated levels of only .01 ppm (Com. 28), others indicated levels as high as 20 ppm (Com. 31; Ex. 39-3). Furthermore, it appears that protective measures vary from lab to lab (Tr. 3157). One chemist, who worked frequently and for several hours a day with benzene during his six years in a research lab that he described as "one of the most prestigious research institutions in the country," testified that employee exposures were not measured, hoods were not used, and there was no medical surveillance program (TR 3492-6). Moreover, there does not appear to be any firm basis to believe that training alone in handling of chemicals adequately protects all laboratory employees from the hazards of exposure to benzene.

Based on the above evidence, OSHA believes that laboratory employees are exposed to the leukemogenic hazards of benzene and, therefore, must be covered by this standard. OSHA does not subscribe to the view that laboratories should be exempted from the benzene standard and that protection for employees exposed to benzene should await promulgation of separate regulations for all chemicals used in laboratories. OSHA is not currently developing a laboratory standard, and the result of exemption of laboratory workers from the benzene standard would, consequently, deprive them of the necessary protection against the hazards of benzene exposure for some time to come. Furthermore, the provisions of the standard relating to methods of compliance are performance oriented and, therefore, will encompass the suggested special requirements for laboratories. For example, the requirement that the employer institute engineering controls and work practices could be met by laboratories in many instances through the use of properly designed hoods. Also, the inclusion of an action level will minimize the monitoring and medical surveillance requirements in laboratories where employee exposure measurements indeed are low.

Although OSHA has not included special provisions just for laboratories, the provisions of the standard accommodate several of the suggestions of the participants, as noted above. Those laboratory operations where benzene exposure levels are at or below the action level will need to be monitored only initially, and medical surveillance of employees engaged in those operations will not be required. When benzene is sealed in containers, the laboratory employer will be required only to train his employees in the hazards of exposure to benzene, and assure that the container is properly labelled, and provide protective clothing where necessary.

Coke Oven Batteries

Steel industry participants requested an exemption from the benzene standard for coke oven workplaces which are covered by the coke oven emissions standard. Although coke oven emissions at coke oven batteries are regulated by § 1910.1029, it is OSHA's view that there is a need to apply to these workplaces the requirements of the benzene standard, as well. The coke oven standard regulates the benzene soluble fraction of total particulate matter present during the carbonization of coal for the production of coke to protect workers from the risk of developing cancer of the lung and urinary tract. The coke oven standard, however, was not designed to protect coke oven employees from the hazards to the hematopoietic system which can result from exposure to benzene. Benzene exposure can occur from leaks in the ovens or in the collection system or from residual vapors left in the ovens when they are opened and the hot coke is pushed out (Little study, B-21). Accordingly, in order to protect workers from the hematopoietic hazards presented by exposure to benzene, OSHA has concluded that inclusion of all coke oven workplaces in the benzene standard is necessary.

The coverage of coke oven workplaces by both the benzene and the coke oven emissions standard does not create a conflict. OSHA believes that the engineering controls required by the coke oven emissions standard will, in all likelihood, reduce exposures to benzene below the action level. In such a case, the benzene standard will impose on coke oven workers only the burden of conducting initial measurement, retaining a record of that measurement, and the training of employees in the hazards of benzene.

SEALED CONTAINERS

The final standard applies only to the labeling requirements and the training requirements to the storage, transportation, distribution and sale of sealed, intact containers. This is a change from the proposed standard, and the emergency temporary standard which would have applied all the requirements of the benzene standard although benzene were "present" solely in sealed containers. The change in the final standard was made in response to comments to the effect that closed containers of benzene pose no threat of exposure to employees (Com. 10). Participants in the rulemaking pointed out that coverage of closed containers would result in employers being required to monitor exposure and make medical surveillance available to employees, such as maritime employees occasionally handling small quantities of benzene in breakbulk form (i.e., drums or packages) (Com. 35), employees of receiving docks and warehouses, and employees involved in inter- departmental transfers of the containers (Com. 28). Additionally, such coverage would also apply the requirements of the benzene standard to employees of retail stores that sell products containing benzene.

Most participants requested exemption of closed containers (Com. 10, 28, 35) without distinguishing between closed and sealed containers. A state agency comment, however, suggested that only "sealed" containers be exempted (Com. 67). OSHA concurs in the view that properly closed containers do not present a health hazard to employees which warrants application of the monitoring and medical surveillance requirements. OSHA, however, is concerned that containers may, after being opened, be closed in such a fashion as to expose employees to a hazard. For this reason, OSHA has adopted the suggestion that the exemption apply only to *sealed* containers, intending by the use of that term to exempt only containers of benzene which are closed in such a manner as to contain the benzene vapors. However, since sealed containers may, during handling, develop leaks (Tr. 3051-2) and thus expose employees to the hazards of benzene, the exemption is further limited to intact containers. Therefore, where the breakage of the container occurs, employers will be required to monitor and to comply with any other applicable provisions of the standard. To assure that all employees are aware of the hazardous nature of the contents of the containers they are handling and because at some point in downstream occupational activities the containers will be opened, the standard applies the training and the labeling requirements to sealed containers. Finally, it should be noted that the regulation of sealed containers in this standard is consistent with that in other caracinogen standards; §§ 1910.1003-1910.1016 exempt sealed containers from their requirements, except for labeling and transshipment.

Definitions: paragraph (b). The standard contains some appropriate definitions. The purpose of providing definitions for key terms is to clarify the intent of those terms as used in the substantive provisions of the standard. All of the definitions of the proposal have been retained in the final standard.

A new definition has been added to those contained in the proposed standard. This is the definition of "Action level." Action level is defined as a concentration of benzene of 0.5 ppm over an 8 hour workday. Industry participants recommended that monitoring be conducted only where exposure exceeds the permissible exposure limits (PC 36, AISI brief, p. 74). OSHA does not agree. It is generally acknowledged that worker exposure to airborne emissions can vary from day to day in a random fashion. This variation in levels is unavoidable; it is only minimally connected to the precision and accuracy of the method of measurement and does not include variations due to wind, temperature and other environmental factors.

Therefore, even though individual measurements of exposure levels may fall below the permissible limit, some possibility exists that on unmeasured days the employee's exposure may exceed the permissible limit. Thus, the concept of an action level provides, statistically, a means by which the employer may assure himself that his employees will not be exposed to benzene over the permissible exposure level (PC No. 14g, p. 5). In view of these considerations and in order to provide a greater degree of employee protection, OSHA has incorporated in the permanent benzene standard an action level of 0.5 ppm.

For those employees whose exposure level is determined by initial monitoring to be below 0.5 ppm, the employer need not do any further monitoring unless a redetermination of exposure is necessitated because of a process, control or personnel change. For these employees, moreover, the employer is not required to provide medical surveillance. The employer, however, must train these employees, label his benzene products, provide protective clothing where necessary, and retain a record of the initial determination and, if any, record of the redetermination measurement.

Employees whose exposure measurements are above 0.5 ppm, but below 1 ppm must be monitored quarterly and provided with medical surveillance. Where exposures are above the action level but below the permissible exposure limit the requirements for regulated areas, methods of compliance and respiratory protection do not apply but the employer must comply with all other requirements of the standard.

Those employees whose measurements are above 1 ppm must be monitored monthly. All the provisions of the standard, moreover, apply where employees are exposed above the permissible exposure limits.

OSHA has, as suggested by some participants (Com. 46), clarified the definition of benzene to include solids which contain benzene. Some comments suggested that benzene be defined as commercial or high grade benzene (Com. 48, 59, 76). OSHA has not adopted this suggestion because of record evidence to the effect that low concentrations of benzene do not necessarily result in low exposures. Other comments suggested that a definition of benzene exposure be included (Com. 36, 57, 59). The thrust of these suggestions was to limit the application of the proposal's monitoring requirements which applied to workplaces "where benzene is present" and the proposal's medical surveillance requirements which applied to "all employees who are or will be exposed to benzene." For the reasons stated below in the appropriate parts of this preamble relating to these requirements, OSHA has not adopted this suggestion.

A new definition of emergencies was added to the standard to clarify the type of situation requiring the use of a respirator. The definition of emergencies also clarifies the situations in which employees shall be provided with a biological screen.

PERMISSIBLE AIRBORNE EXPOSURE LEVEL. PARAGRAPH (c)(1)

Based upon a thorough review and evaluation of evidence in the record, OSHA has, as stated above, concluded that benzene:

(1) Is a human leukemogen;

(2) Causes bone marrow depression resulting in alterations in peripheral blood; and

(3) Causes chromosomal damage in blood cells.

These conclusions are based on studies ranging from single case reports to

retrospective mortality studies and also experimental evidence. These studies represent the best available evidence upon which OSHA must make a decision. This decision is not predicated on any particular study, but is based on an assessment of the entire set of evidence taken as a whole.

OSHA recognizes that only recently has there been a well-designed study which may indicate a leukemogenic response among benzene-exposed animals. (Nelson, Ex. 178) In any event, the best evidence to date is that based on direct human experience. Based upon such evidence, OSHA concludes that benzene is and must be regulated as an occupational carcinogen.

Comment and testimony from industry for the most part, does not dispute the leukemogenic potential of benzene (e.g. Eckhardt, Ex. 115.B. 1, pg. 3; Tabershaw Tr. 2545). However, industry argues that this relationship is valid only at high exposure levels. In support of this view, they cite as evidence that: (a) the documented cases of benzene-induced leukemia were among employees who were, most probably, exposed to high concentrations, and (b) that several studies of undefined numbers of workers who may have been exposed to low levels of benzene did not demonstrate a leukemia excess (The benzene studies are described under Health Effects: Leukemia). Industry also believes that observable blood disorders precede the development of benzene-leukemia and that such hematological abnormalities are reversible (ORC, PC 34, p. 2; Tabershaw Tr. 2543 Jandl. PC 26B, Allied P.C. 22, p. 7). They conclude that the present exposure limits of 10 ppm TWA and 25 ppm ceiling are sufficiently protective to guard against the development of non-malignant blood disorders and, consequently, that limiting exposure to such levels will also protect against leukemia. (ORC, PC 34; Jandl, PC 26B; Tabershaw, Tr. 2546.)

The issue of the levels at which cancer is induced by chemical agents and whether or not there is a "threshold" has been a major issue in every OSHA rulemaking concerning the regulation of occupational carcinogens (See preambles to Carcinogen standard (39 FR 3758); Vinyl Chloride (39 FR 35892); Coke Oven emissions (41 FR 46742). The benzene hearing was no exception. As in the case of arsenic, the lack of an unequivocal animal model (Kraybill, Tr. 758) requires that the Secretary's decision rely primarily on data obtained from human evidence. However, the epidemiologic method is by its very nature, a retrospective view of the evidence, i.e. findings of a recent excess of mortality among workers may relate to initial exposures occurring as much as 20 years or more previously and which most certainly correlate to exposures at higher concentrations than present levels. Because of these variables, it is extremely difficult to derive definite conclusions as to the quantitative health risk to the workers at exposures near 1 ppm. Studies which report negative findings, such as those studies conducted by Stallones, Tabershaw-Cooper and Thorpe suffer from the disadvantage of not being able to clearly define an exposed cohort, i.e. the indentification of a group of workers actually exposed to benzene and to what levels they were, in fact, exposed. (Stallones, Ex. 115.C; Tabershaw-Cooper, Ex. 149A; Thorpe, Ex. 2-34). OSHA recognizes that it is extremely difficult to reconstruct and define employee exposures retrospectively. Therefore, given the uncertainty of the definition of exposure and the potential for dilution of mortality excess among those actually exposed to benzene and other methodological deficiencies, OSHA is reluctant to place substantial reliance upon these negative reports. Thus, there is little definitive information available pertaining to the leukemogenic risk of an adequate size cohort of workers exposed to benzene less than 10 ppm and who have been followed for an adequate amount of time. Furthermore, it is OSHA's view following a careful review of the record that, at the present time, it is impossible to derive any conclusions regarding dose-response relationships for benzene (Goldstein, Ex. 75, p. 2 NRC, Ex. 2-4 p. 11) beyond the general observation that higher exposure levels carry a greater risk than do lower exposure levels. What is apparent however, is that a decrease in exposure level and/or duration will result in a decreased risk of leukemia.

OSHA also recognizes that, in some published cases with adequate documentation, leukemia attributable to benzene exposure developed after observable changes in the peripheral blood, i.e., various cytopenias, pancytopenia and/or aplastic anemia. (Goldstein, Ex. 43B, p. 166.) However, many cases of benzene-induced leukemias were recognized as such only after a patient with overt physical symptoms presented himself to a physician. Similarly, Snyder stated that, in the cases of pancytopenia and aplastic anemia, individuals "exposed to benzene usually do not approach their physicians until late stages in the disease." (Ex. 156.2, p. 2.) As a result, the hematological picture before the onset of disease is often not known. Moreover, because of the well-known reserve proliferative capacity of the bone marrow it is possible that marrow damage may occur without being reflected in the peripheral blood. (Goldstein, Ex. 43.B, p. 175; Wintrobe, Ex. 2-107, p. 676.) Olson acknowledged that alterations in bone marrow activity can occur despite a normal blood count (TR. 2894). Moreover, Goldstein noted that some individuals may have significantly depressed blood values, and yet remain within normal ranges. For this reason, a pancytopenic response to hematotoxic agents may go unrecognized. Therefore, OSHA believes that the scientific evidence is insufficient for adoption of the hypothesis that a preceding prodromal blood syndrome is a necessary prerequisite for the development of benzene leukemia. In this regard, Goldstein in his testimony cautioned that benzene may act as a direct-initiator of a neoplastic response.

OSHA is also aware that in many instances, non-malignant blood disorders resulting from chronic exposure to benzene may be reversed by removal from benzene exposure. However, the apparent high degree of reversibility, as set forth in Jandl's review, is open to question as pointed out in the Health Effects section.

Furthermore, a most characteristic finding which pervades the published literature, is that physiologic factors which cannot be identified a priori, such as nutritional state, genetic constitution, variations in metabolism of benzene and exposure (both occupational and non-occupational) to other marrow depressants, and the variables of age and sex may act to modify the individual's response. (Browning, Ex. 31, pp. 26 ff; Shaw, Tr. 421; Snyder, Ex. 156, p. 2.) For example, Browning stated, "• • • [t]here is no doubt that both men and women differ markedly in their response to similar conditions of exposure." (Ex. 31, p. 2.) Therefore, unqualified identification of high-risk subgroups cannot be made at present. Because of these uncertainties, this standard is designed to protect the most sensitive as well as the more resistant members of benzene-exposed worker populations by limiting exposure to the maximum extent feasible.

It is, therefore, clear from an examination of the record that a determination of a precise level of benzene exposure which presents no hazard cannot be made and that the corollary question of whether a "safe" level of exposure to benzene exists cannot be answered. The agency is aware of and has examined scientific opinion and data submitted by industry that thresholds for carcinogens may exist. However, prudent public health policy requires a conservative course of action until such evidence is of a definitive nature.

In its conclusionary document the International Workshop also stated: "[t]he workshop discussed but could not agree on whether there was a concentration below which there would be no leukemogenic effect clearly attributable to benzene" (Ex. 17, p. 7). Kray-

bill testified that because there was not enough data at the lower part of the dose-effect curve, he was unable to estimate a "safe" level. As early as 1939, in presenting data on the effects of chronic benzene exposure including leukemia, Hunter stated: "It is doubtful whether any concentration of benzene greater than zero is safe over a long period of time." (Ex. 2-74, p. 354.) In 1974, the MAK-Werte Working Group stated, * * * [O]n the proven carcinogenic (leukaemogenic) effects of benzene and the lack of quantitative measuring data in the low concentration ranges, it is not possible at this time to establish an MAC (maximum allowable concentration) which might be regarded to be without danger." (Ex. 2-58, p. 52.)

Goldwater testified that zero is the level at which there is no risk of getting cancer from benzene (Goldwater Tr. 2500).

Goldstein stated; "As we do not know what the safe level is, the standard would appear to me to be based, must be based on prudent medical approach, which is to keep it at the lowest feasible level" (Tr. 352).

Aksoy stated; "[F]or me, the permissible exposure limit for benzene should be zero. Where it is technically impossible to achieve this, the permissible exposure limit should be lowest possible" (Tr. 149). In OSHA's view, the demonstration of cancer induction in humans at a particular level is not in the regulatory context, a prerequisite to a determination that a substance represents a cancer hazard for humans at that level. Relying upon a subsfantial body of scientific opinion, OSHA has concluded that, when dealing with a carcinogen, no safe level exists for any given population. For example, the National Cancer Institute's Ad Hoc committee on the Evaluation of Low Levels of Environmental Carcinogens (1970) states.

> no level exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents, a "safe level for man cannot be established by application of our present knowledge." (Ex. 272, p. 1.)

Thus, OSHA takes the position that in promulgating a health standard for a life threatening hazard such as benzene-induced leukemia, the exposure limits be established on a conservative basis so that worker health is properly safeguarded.

From the point of view of choosing a safe level of exposure, therefore, the permissible exposure limit should be set at zero. However, based on the evidence in the record, it is OSHA's judgment that a zero standard for exposure to benzene is not technologically feasible. In fact, it is clear that certain quantities of benzene are present in the ambient environment as a result of natural phenomena and as artifacts of human activity. While a permissible exposure limit equal to zero plus background would represent the lowest level theoretically possible, OSHA believes that the record shows such an approach is not feasible. Even if such a number could be determined, achieving a standard of zero plus background would require that exposure to benzene be effectively zero so as not to increase employee exposure above background levels. There has been no evidence presented that convinces OSHA that such a complete elimination of benzene in all industries can be achieved by existing or future technology. In determining the apropriate permissible level of employee exposure to benzene, OSHA relies in part on the record of this proceeding and in part on policy considerations which lead the Agency to conclude that, in dealing with a carcinogen or other toxic substance for which no safe level of exposure has been demonstrated, the permissible exposure limit must be set at the lowest level feasible. Such a determination involves a measure of subjective judgment which OSHA believes is justified by the nature of the hazard being dealt with, and the intent of the Act. Section 6(b)5 provides that the standards for toxic substances shall be feasible. That section specifically provides that:

> In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

OSHA has determined that 1 ppm TWA, 5 ppm ceiling limit for 15 minutes is the level which most adequately assures, to the extent feasible, the protection of workers exposed to benzene. In making this determination, the Agency recognizes that many industries affected by this standard have already achieved this permissible exposure limit, in a good many of their operations. As shown below for worksites currently above these values, currently available engineering controls and/or modifications of work practices can effectively reduce employee exposure to below the 1 ppm TWA, 5 ppm ceiling. This might suggest that the lower permissible exposure limits could be established, if not for all, at least for some of the industries covered by the benzene standard. OSHA has considered the appropriateness of establishing lower permissible limits for those industry sectors which can acheive these lower limits. It is, however, difficult on the basis of the available evidence to make this determination. The benzene standard applies to a multiplicity of industries and exposures occur from such varying sources as leaks in closed systems to batch operations using solvents. Identification of some operations with lower exposure levels is possible in some industries, but even for these industries exposure information is not available for all operations. Moreover, even where information has been furnished by particular employers as to exposure levels for operations in their plants, it is not possible with any degree of confidence to apply this information to operations of another facility in the same industry. There is a great deal of variability in the configuration of plants, and the physical location of operations within a plant varies from facility to facility. Finally, it is OSHA's view that different levels for different industries would result in serious administrative difficulties. Because of these widespread differences and diversity, OSHA has decided to apply to all affected industries a permissible exposure limit of 1 ppm. Several industrial situations have been examined in making this determination and are discussed below.

Oil and gas production work is conducted in outdoor open air environments with relatively low-benzene content (Tr. 1463) streams maintained in closed systems. (Tr. 1463). Employee exposures in producing operations are intermittent and extremely low (PC 33API Brief p. 141; Ex. 116). Evidence in the record indicates employee exposures ranging between 0 ppm and 2 ppm, with over 80% of the measurements below 0.25 ppm. (Tr. 1467, Ex. 116, Ex. 115.A.4, p. 8). Since the production of crude oil and natural gas occurs in completely enclosed systems, the only employee exposures result from leaking valves (P.C. No. 30) and, as already indicated, these exposures are minimal. Visual inspections can detect these malfunctions and correction can be accomplished largely through replacement of seals. Engineering controls in the form of "double sealed" or "canned" pumps could also be instituted to avoid the leaks.

Pipeline transportation of crude oil and refined products is primarily a closed system operation (Tr. 1460). Potential employee exposure may occur where the products are transferred by truck or rail. (Tr. 1471.) Other operations involving employee exposure are gauging, and sampling operations, all of which are of relatively short duration with minimal employee exposures (Tr. 1472). Measurements taken by industry indicate that most such exposures on an 8 hour TWA basis are below 0.5 ppm. (Ex. 115, A.1.) The only area in which exposures were shown to exceed the permissible exposure limit was in the additive handling operations in which benzene was being utilized as a diluent. Since benzene was not necessary to the process, it was being eliminated from that operation (Tr. 1473).

The unloading and loading of gasoline, crude oil, and other refined products from marine vessels results in limited exposure to shoreside personnel ranging between 0.01 ppm. to 0.82 ppm. with an 8 hour TWA of .2 ppm. (Tr. 2271.) The shoreside personnel's potential for exposure occurs during the connecting and disconnecting of the hoses and loading arms, an activity of limited duration. (Fuller Ex. 115, A.3, p. 4.) The unloading and loading of benzene from marine vessels, however, may result in higher employee exposures. The transportation by barge accounts for the majority of the total benzene transported. (A.D. Little, Ex. 5A, 4.24, 4.42.) The connecting and disconnecting, opening and closing of valves and the monitoring of fill levels are the typical operations in which employees will actively be involved. These operations are all of limited duration and, consequently, employees would spend little of their time involved in them. The remainder of the employees' time would be spent elsewhere removed from exposure. Therefore, work practice controls would be extremely effective in reducing employees' exposures to benzene during the unloading and loading of marine vessels. (A.D. Little Vol. 1, May 1977 p. 4.27.)

One methodology discussed to reduce exposure to vapors is a marine vapor recovery system (Fuller, Ex. 115-A.3). However, at the present time, questions concerning fire and explosion risk, and potential structural damage to barges have, not as yet, been adequately resolved.

The exposures measured during the unloading of gasoline at bulk terminals are low. Sexton, an industry spokesman, reported that the highest long-term samples on individual truck operators was 0.41 ppm., with the vast majority being below 0.2 ppm. (Ex. 115-A.10.) These terminals from which the exposure data was obtained represent examples of the various types of truck loading techniques and different physical characteristics of the terminals, such as loading rates, covered versus uncovered loading racks, and floating roof tops.

Data presented by Williams Pipeline also showed exposure levels, for the most part, below 0.5 ppm. on an 8 hr. TWA basis. It, therefore, appears that one or a combination of these available engineering controls will be sufficient to reduce employee exposure below the permissible exposure limit.

Approximately 94% of the benzene produced is derived from petroleum through the process of catalytic reforming, recovery from pyrolysis of gasoline and hydroalkylation of toluene. Many of the processes used to produce benzene involve completely enclosed units such as reactors. However, these processes do contain vents and other sources of leaks, which can result in significant exposures (A. D. Little, Vol. II-B11).

Control of emissions can be accomplished by such activities as removal and reinstalling equipment such as pumps, compressors, machining of parts, cutting and welding of piplines, fabrication of equipment, replacement of gaskets. Also, the use of automatic gauging devices, closed loop sampling systems, vapor recovery units, floating roof installations and rupture discs has been suggested (Ex. 5A, 4-53).

The majority of employees exposed at petrochemical plants are already within the permissible exposure limit. (Ex. 111-A, pp. 4-7.) At only four of twelve plants surveyed, exposures were above 1 ppm. (ADL. May 1977 p. 10, Table 2), and of those four plants only two were above 5 ppm. The fact that eight of those twelve plants were already within the permissible exposure limit suggests that other plants can be rehabilitated with existing technology to achieve levels within 1 ppm.

The record indicated that exposures to benzene vary between 0.1 ppm and 20 ppm. (Com. 28, 31). The differences in exposure levels appear to be due to the particular protective measures employed in the laboratory. (Tr. 3157, 3492-6). On the basis of this evidence, OSHA has determined that the use of a properly operating laboratory hood is one available engineering control which is currenty reducing employee exposures (See ADL 4-41) well below the permissible exposure limit. The type of control selected will be dependent upon the individual laboratory. (ADL May 1977 pp. 4-40 and 4-41.)

The two segments of the steel industry wherein benzene exposure occurs are the coke oven battery and the light oil distillation plants. Exposures at the coke oven batteries range between 0.02 ppm and 0.31 ppm. (Ex. 135 p. 4 and Attachment 2). It is thus apparent that the steel industry's compliance with the Coke Oven Emission Standard will maintain benzene exposures well below the action level.

Within the distillation plants, equipment is used to distill the benzene out of the light oil. It is in this operation that the steel industries claim that in certain situations it will not be feasible to reduce exposures through engineering controls. It appears, however, that those situations are limited to the older "coke driven by-products plants" (between 30, 40, and 50 years old). (PC 36 AISI Brief, p. 87-88) and does not exist for the newer plants which currently have low exposure levels.

As the Courts of Appeals have emphasized, OSHA is not restricted to the status quo. Standards may be set which require improvement in existing technologies or which require the development of new technology and OSHA is not limited to setting standards based solely on devices currently available, at least where new technology appears on the horizons to limit exposures below the permissible exposure limit. (See e.g. *Society of Plastics Industry* v. *U.S. Department of Labor*, 509 F. 2d 301 (C.A. 2. 1975) cert. denied.) Certainly here, the evidence indicates that technological controls to reduce exposures, if they are not universally used, do exist (Ex. 5A, 4-37).

Benzene exposure may occur in a variety of industries when solvents containing small quantities of benzene are utilized. Some examples are the rubber industry, the manufacture and use of adhesives, paint manufacturing and application, metal can production and commercial printing. Evidence in the record indicates that, with the exception of paint remover firms for the most part have restricted the use of benzene as a raw materials. It appears, therefore that the percent of benzene coupled with presently available engineering controls, such as local exhaust systems, results in minimal employee exposures, (May 1977 ADL p. 4-27, 4032).

Based on the record of the benzene rulemaking, OSHA has concluded, as indicated above, that the permanent benzene standard is technologically feasible. Furthermore, OSHA has determined that this standard better effectuates the purposes of the act than the national consensus standard for benzene.

Dermal and Eye Exposure Limits: Paragraph (c)(2). The final standard, like the emergency temporary standard and the proposed standard, prohibits all eye contact and skin contact with liquid benzene. This requirement is based on OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (i.e. inhalation, ingestion, and skin absorption) be limited to the extent feasible.

Although the record evidence does not conclusively establish what the effects of contact with benzene are on the eyes or the skin, participants generally did not oppose a requirement for restricting such contact. Indeed some participants indicated that they already provide protective clothing and equipment to their employees in order to protect them from possible hazards of contact with liquid benzene.

The record evidence on the effect of liquid benzene on the eyes or the skin is extremely limited. No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans (Ex. 2-46, 2-47, 2-48, TR 2459-90) are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative

rate of absorption through damaged skin (TR. 2469-70). Testimony as to skin absorption of benzene was given by NIOSH and by an industry expert witness. NIOSH's view is that benzene is readily absorbed through the skin although the extent of absorption in any particular exposure is unknown. NIOSH however, believes that in instances of an inflamed skin or when benzene is contained in a mixture a "considerable amount" can be absorbed (TR-860). Industry's witness stated that he had no personal view as to whether benzene is absorbed through the skin (TR. 2469) nor whether the rate of absorption of benzene was or was not increased where the benzene is a component of a solvent (TR. 2471-2). The witness also pointed out that he did not know the effect of multiple applications of benzene on the broken skin (TR 2471). He suggested that additional studies be conducted to resolve these issues. This witness nevertheless testified that liquid benzene can damage the outermost protective layer of the skin (TR 2470) and that, although there is no verifying data, "it is ordinarily assumed that penetration of any molecule will be greater through damaged skin that undamaged skin" (TR 2469).

In order to assure that employees are adequately protected against all benzene hazards, it is OSHA's belief that it is appropriate to provide precautions against eye and dermal contact with benzene. In reaching this conclusion, OSHA has taken note that the threshold limit value for benzene adopted by the ACGIH for 1976, and the intended change of that TLV, bear a "skin" notation which refers "to the potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye, either by airborne, or more particularly by direct contact with the substance. Vehicles can alter skin absorption. This attention-calling designation is intended to suggest appropriate measures for the prevention of cutaneous absorption so that the threshold limit is not invalidated" (TLVs for chemical substance in Workroom Environment with Intended Changes for 1976, p. 5). OSHA further notes that maximum allowable concentrations of benzene in other countries also carry a "skin" notation.

OSHA has reviewed the various suggestions for changes in some of the requirements of the provision on eye and dermal limits. Some participants suggested that the provision apply to "liquid benzene" to make clear that the limitation did not apply to eye and skin exposure to benzene vapors (For example, see Com. 53). OSHA has adopted this suggestion since it was never intended that the provision apply to other than liquid benzene. Some comments suggested that the limitation apply only to liquid benzene of a commercial grade or higher (Com. 48; Com. 76) so as to exclude solvents with trace amounts of benzene (Com. 59). There is no evidence, however, to suggest that the absorption rate depends on the amount of benzene present in the liquid (TR 2472, 2482).

Regulated Areas: paragraph (d). The final standard contains requirements for regulated areas. The purpose of establishing regulated areas is to limit the exposure at above 1 ppm to as few employees as possible. The burden of the regulated area provison on the employer is expected to be minimal since the provisions require the employer merely to identify and control access to regulated areas and to notify the applicable OSHA area office of their existence and condition.

The standard requires that regulated areas be established where airborne exposures are above the permissible exposure limit and that access thereto be limited to authorized persons. Regulated areas must be established at all worksites where the permissible exposure limit is exceeded. Although transportation was not specifically listed in the proposed regulated area paragraph, the regulated area requirements of the permanent standard apply to the transportation of benzene, as well as to workplaces where benzene is produced, reacted, released, packaged, stored, handled or used. The scope of the regulated area subparagraph is, therefore, identical to the scope of the standard. This identity of scope has the result that, while the loading of gasoline at the bulk terminals may require the designation of a regulated area, the transportation of the gasoline from the terminals does not, in as much as that transportation activity is exempted from the standard.

Some participants misunderstood the regulated area requirement in the proposal and thought that regulated areas must be established even where exposures are below the permissible exposure limits. (Tr. 3136.) The standard, however, requires establishment of regulated areas only where exposures are above 1 ppm as an 8 hour time weighted average or 5 ppm averaged over a 15 minute period.

Some participants recommended that regulated area requirements not apply to laboratories (Ex. 6, No. 37, 70) or to coke oven batteries (Ex. 135; p. 2 PH; 36 AISI brief, p. 17). It is OSHA's view that existence of a hazard, rather than the type of operation, should be the basis for establishment of regulated areas. Therefore, if the exposures in laboratories or coke oven batteries were to exceed the permissible exposure limits, regulated areas would have to be established at those facilities. Moreover, OSHA feels that the burden is minimal compared to the protection afforded employees.

The standard requires that the OSHA area office be notified within 30 days following the establishment of a regulated area. Each employer must notify OSHA of the existence of any regulated areas within his establishment and of the conditions existing within such areas. Since regulated areas are required to be established only where exposures to benzene exceed the permissible exposure level, employers whose operations are all below that level need not file the report. This requirement is designed for compliance purposes. One comment suggested that OSHA should require, as it did in the Emergency Temporary Standard on Benzene, notification of the use of benzene in every workplace where it is present (Com. 62). It is clear from the record evidence that benzene is present in some amount or other in a vast number of workplaces and that, consequently, a notification of use provision would be administratively burdensome to OSHA and employers without necessarily resulting in more effective enforcement of the standard. For this reason, the final standard, as the proposal, requires merely the notification of regulated areas. Other comments suggested that laboratories and other small users of benzene be exempted from this notification provision on the ground that their use of benzene is infrequent (Com. 70) and that the filing of this notice by "big users" would be sufficient to set priorities for facility inspections. OSHA does not agree. The amount of benzene used by research and testing laboratories will vary from time to time depending on the projects being worked on. Finally, the suggestion presupposes that facility inspections would be conducted solely on the basis of the frequency of use of benzene. However, even where the use of benzene is infrequent, impairment of employee health may occur particularly where the exposure is above the permissible exposure limit. Other industry comments requested that employers be relieved of notification of regulated areas where temporary regulatory areas of short duration are established for maintenance work or for special projects or when leaks in closed systems occur (Com. 46, 50). In view of the hazardous nature of benzene exposure, OSHA deems it essential to require notification of regulated areas in all cases where employees are exposed above the permissible exposure limit. Moreover, in a facility where there are frequent leaks, the employer will be alerted by the necessity to report these leaks to the possible need to take additional measures to protect employees against such exposures. If the possibility exists that the permissible exposure limit will be exceeded from time to time, the maintenance of a regulated area at the lo-

cation of the leaks will, of course, minimize exposure and minimize the reporting requirement. Some industry participants recommended that the standard include a method for "deregulating" the regulated areas once exposures fall below the permissible exposure limits. (Com. 45, Com. 53, Com. 57) OSHA does not feel that a formal method for deregulation is necessary. Since the standard does not require maintenance of a regulated area except where exposures are above the permissible exposure limit, the regulated area requirement does not apply where the employer has reduced the exposure levels below the permissible exposure limit. Nor would a deregulation procedure contribute to the protection of employees. Moreover, if formal deregulation were required, it would be necessary for the employer to file an additional notification with the OSHA area office should conditions change thereafter and the exposure again exceed the permissible exposure limits. In view of these considerations, a formal deregulation procedure would appear to be unnecessarily burdensome.

Monitoring: paragraph (e). Significant changes have been made in the monitoring section of the final standard in response to comments by participants. Briefly, the final standard requires all covered employers to make measurements to determine whether any employee may be exposed to airborne concentrations of benzene, and imposes different measuring requirements depending on whether exposure measurements are above or below certain levels.

The monitoring requirements are imposed pursuant to Section 6(b)(7) of the Act (29 U.S.C. § 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of monitoring are to determine the extent of exposure, to identify the source of exposure to the hazard and to enable the employer to select proper control methods and evaluate the effectiveness of the selected methods. Thus, monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not exposed to benzene in excess of prescribed levels. Additionally, monitoring enables employers to notify the employees of their exposure level, as required by section 8(c)(3) of the Act, and provides information necessary to the examining physician.

The need to conduct exposure monitoring was generally accepted by participants in the rulemaking process (P.C. 35MCA brief, p. 55-b; P.C. 36; ORC brief, p. 7). Many comments, however, objected to the proposal's requirement to measure airborne exposures in all workplaces "where benzene is present" (P.C. 33; API brief, p. 127a; P.C. 34; ORC brief, pp. 7-8). Participants argued that the use of the term "present" is so broad as to encompass each and every employee at a facility (Ex. 6, No. 53). It was also argued that benzene is present in the ambient atmosphere (Ex. 6, No. 43; Ex. 84B. 18, Ex. 84A, p. 7) with the result that every work operation in every city would probably have to be monitored (Ex. 6, No. 43, p. 12). OSHA's objective is to minimize all occupational exposures to benzene. The term "presence" was used in the proposal to convey the intent that, whenever the exposure of any employee to benzene concentrations resulted from workplace operations at the place of employment, the employer was required to measure that exposure. OSHA does not intend that employees, who might be exposed solely from other sources, such as ambient levels of benzene, be covered by the monitoring requirements. In view of the confusion as to the meaning of the term "presence," the final standard does not use that term but instead specifies the general classes of occupational activities which can result in employee exposure to benzene, and requires monitoring where any of these activities are conducted.

In conducting the monitoring of exposures, the standard does not require that each individual employee's exposure level be measured. Although individual measurement is the ultimate indicator of employee exposure, OSHA believes that a requirement for individual measurements may be too burdensome. Accordingly, the standard requires that the measurements be made by monitoring which is representative of each employee's exposure to benzene over an eight-hour period without regard to the use of respirators. It should be noted that the requirement for representative monitoring does not preclude an employer from taking individual exposure measurements of each of his employees; individual measurements are certainly considered to be representative; and the representative monitoring requirement is the minimum that the employer must meet.

In establishments having more than one work operation involving the use of benzene, the monitoring to be representative must pe performed for each type of employee exposure within each operation. One participant requested that area sampling be permitted in order to lessen the burden and cost of monitoring each employee with a different job function (Ex. 6, No. 49, p. 4). Although the final standard does not specifically require personal sampling, monitoring under the standard must determine breathing zone exposures. Appendix B, IV, therefore, recommends that air sampling be taken in the employee's breathing zone. Area samples are generaly not as direct a measure of employee exposure, and consequently, may not meet the requirement for representative monitoring, although where area sampling can be correlated with breathing zone exposures, area sampling may be used. OSHA, however, notes that while there are techniques to correlate area sampling with breathing zone exposures, these are generally more burdensome than personal sampling and involve much more sophisticated data collection and analysis, including the performance of personal sampling to assure the correlation.

Some participants suggested that employers with several places of employment, in which there are workplaces with identical processes or operations, be permitted to monitor only a representative number of such locations (Ex. 6; Ex. 50, p. 3; Ex. 60, p. 7). The fact that work operations are in different geographical locations would not in itself preclude representative monitoring. However, it is the employer's responsibility to assure that indentification of conditions, characteristics, activities, climate, etc. exist so that monitoring at particular sites would actually be representative of employee exposure at other sites.

The employer is also required to use a method of monitoring and measurement with an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for concentrations of benzene of 1 ppm or more. Methods of measurement are presently available to detect benzene to this accuracy level (Tr. 342-3) and one such method is described in Appendix A, II, E. Industry participants expressed concern that consistent compliance with these accuracy requirements will be impossible. (PC 36; AISI brief pp. 106-108.) The record, however, indicates that, even where benzene is present with other organic solvents, the OSHA Analytical Method will still enable employers to measure low levels of benzene well within the accuracy requirement of the standard. (Tr. p. 343.) Indeed, it was suggested at the hearing that there is an alternate method for sampling, passive dosimeters, which may comply with the accuracy reqirements contained in the proposal. (Tr. 2381.)

As eariler indicated, the standard requires all covered employers to initially measure the airborne exposure of all of their employees. Some participants objected to this requirement and recommended that initial monitoring be limited to those workplaces where there is a probability of exposure to benzene in excess of the permissible

exposure limit (P.C. 36; AISI brief, pp. 73-74; P.C.34; ORC brief; p. 8) or in excess of 10 ppm (MCA brief, p. 50). It is OSHA's view that a "probability" is too speculative where a carcinogen is involved, and that a more definitive basis is needed for determining employee exposure. It is, therefore, OSHA's decision to require initial monitoring at any level of exposure to a carcinogen. Initial measuring of exposure is necessary for the protection of employees particularly where, as here, the permissible exposure level is not a "safe" or "no effect" level but is predicated upon feasibility. Moreover, initial monitoring does not place an undue burden on the employer since he need not continue the monitoring for those employees whose exposures are below the action level.

The standard requires that the initial monitoring be conducted and the results thereof obtained within 30 days of the effective date of the standard. Several comments requested that a longer period, ranging between two months (Ex. 176) to six months (P.C. 36; AISI brief, p. 75; TR 3137), be allowed for employers to meet this requirement. OSHA has retained the thirty day requirement. Since the final standard has a delayed effective date of thirty days after date of publication in the FEDERAL REGISTER, employers will have sixty days to comply with this requirement. OSHA feels that this period is sufficient to enable employers to secure sampling equipment, take samples, and obtain the results. Moreover, the standard permits employers, who have monitored within the last year, to utilize these measurements for purposes of compliance with the initial monitoring requirements, provided that the sampling and analytical method used meets the accuracy test of this standard and provided that the employer maintains a record of these measurements and notifies employees of their exposure levels. Employers who have already monitored their employees' exposures within this period will, therefore, not have to conduct initial monitoring unless, because of a process, control or personnel change, they are required to redetermine exposures. In addition, to the extent that the initial monitoring requirement cannot be complied with because of the unavailability of professional or technical personnel or of materials or equipment, the temporary variance procedures of the section 6(b)(6)(A) of the Act may be appropriately utilized. As noted, however, it is not expected that this will be generally necessary.

The frequency of monitoring employee exposure has been modified in the final standard. The proposal would have required monthly monitoring where exposures were above the permissible exposure limit and quarterly monitoring of those employees whose exposure was below that level. The final standard does not require employers to repeat the monitoring where the initial measurements are below the action level, unless there is some change in operations which might alter the exposures. Where the exposure measurements are above the action level but not in excess of the permissible exposure limit, the employer is required to monitor quarterly. Where initial or subsequent monitoring indicates that exposures are above the permissible exposure limit, the employer must monitor monthly. In developing these requirements, OSHA has given serious consideration to the numerous suggested modifications of the proposal's requirements. These ranged from suggestions to lessen the frequency of repeated monitoring to suggestions that monitoring frequencies should depend on whether the process is stable or highly variable (Ex. 6, No. 40), or should be based on performance variables, such as frequency of use, quantity used (Ex. 6, No. 70) and engineering controls (Ex. 6, No. 12, No. 43), or should be at the discretion of a professional (Ex. 6, No. 43). Some participants objected to periodic monitoring where initial monitoring reveals exposures below the permissible exposure limit (P.C. 36; AISI brief, p. 76; Com. 36, 10, 37). OSHA agrees that periodic monitoring is not necessary where exposures are shown to be below the action level. Accordingly, OSHA has eliminated the repeat monitoring requirement for operations below the action level. Where initial measurements are above the action level but do not exceed the permissible exposure limit, periodic monitoring is necessary to assure that exposures remain within that range and do not rise to above the permissible exposure limit. OSHA believes that quarterly monitoring is sufficient to detect substantial changes in exposures and to assure that employee exposures remain below the permissible exposure limit. Some participants objected to monthly monitoring where initial measurements are above the permissible exposure limits (P.C. 36 AISI brief, p. 76, Ex. 6, No. 50). Their rationale is that repeat monitoring serves no purpose since the hazard has already been identified (Ex. 170). They argued that the requirement to establish regulated areas where exposures are above the permissible exposure limit is a sufficient incentive for employers to remonitor a workplace as soon as they believe that the exposure has been reduced (P.C. 36 AISI brief, p. 76-7). As previously pointed out, monitoring serves other purposes than initital determination of employee exposure. Monitoring is a check on the efficiency of engineering controls: increased levels alert the employer to the need to check and possibly alter these controls. Increases in benzene levels may also necessitate changes in types of respirators. Exposure measurements remind employees and employers of the continued need to protect against hazards, and are also useful to the examining physician in determining whether the exposed employee is at an increased risk. OSHA, therefore, is of the view that repeated monitoring, where initial measurements are above the permissible exposure limit, is necessary to protect employees. Other participants expressed the view that this monitoring should be less frequent than monthly—that is, should be quarterly (P.C. 31 ORC brief, p. 9; L.C. 3); semi-annually (P.C. 36 AISI brief, p. 78; Ex. 6, No. 57), annually (Ex. 6, No. 59, No. 76), or as frequently as significant changes are believed to have occurred (L.C. 19). In view of the leukemogenic hazard of exposure to benzene, it is OSHA's view that monthly monitoring, where exposures are above the permissible exposure limit, is necesary to protect the health of exposed employees.

The final standard also provides that employers may discontinue monitoring for those employees for whom two consecutive measurements taken seven days apart show exposures to be below the action level. Where employee exposure measurements fall below the permissible exposure limit but are at or above the action level, the employer may alter the monitoring schedule for those employees from monthly to quarterly after two consecutive measurements taken seven days apart indicate the reduction in levels.

The standard further requires that, whenever there has been a production, process, control, or personnel change which may result in new or additional employee exposure, or whenever the employer suspects that a change of employee exposure may occur, the employer must repeat the required monitoring. Redetermination of exposures in such instances is necessary so that the employer may take the necessary action to protect his employees, such as providing appropriate respiratory equipment, or instituting engineering controls. Redetermination is required only where there is a new exposure or an increase in exposure levels is suspected (Ex. 6, No. 76, No. 50). The required redetermination where there is a change of personnel was added to the final standard in view of evidence that exposure levels can change when different employees perform the work (Tr. 3093). This requirement does not mean, however, that the employer must remonitor every time there is a personnel change but he must redetermine exposures when the work practices of the substitute employee are such that an increase in exposure may

result. Redetermination of exposure must also take place after the cleanup of spills and the repair of leaks, ruptures or other breakdowns. One comment suggested that redetermination not be required in these instances (L.C. 19). OSHA has not adopted this suggestion. Spills, leaks, etc., can result in very high exposure levels (Tr. 1299; P.C. 30, p. 48), and the requirement to redetermine exposures after cleanup or repair provides one method of ascertaining that proper corrective methods have been instituted and employee exposures are not significantly altered.

The final standard further requires that employers notify each of their employees of the exposure measurement which represents that employee's exposure. This requirement is discussed in detail under Recordkeeping.

It should also be noted that paragraph (m) of the standard requires the employer to allow employees or their designated representatives an opportunity to observe the monitoring. The specific provisions of paragraph (m) are discussed below.

Methods of compliance: paragraph (f). The final standard, as the proposed standard, requires employers to institute engineering and work practice controls to reduce employee exposure to benzene to or below the permissible exposure limits, except to the extent that such controls are not feasible. This requirement is in accord with OSHA's policy that feasible engineering and work practice controls must be used as the primary methods of reducing employee exposures. This policy is based on the view that the most effective means of controlling employee exposures is to contain concentrations at their source through use of mechanical means combined with work practices rather than reliance on the variability of human behavior so critical to the successful use of respirators. Thus, the standard also provides that, in situations where feasible engineering controls and work practices are insufficient to reduce exposure to the permissible limits, the controls must nonetheless be used to reduce exposures to the lowest achievable level, and then be supplemented by the use of respiratory protection.

In reaching the decision to require engineering and work practice controls as the primary methods of reducing benzene exposures, OSHA has carefully considered the objections of various participants. While recognizing that in many situations engineering and work practice controls are the preferred methods of reducing exposures to or below the permissible levels, several participants recommended that the hierarchy of control measures be eliminated and employers be allowed the freedom of selecting the control measure to be instituted. (Tr. 3140). These participants particularly objected to the requirement that engineering controls and work practices be used to reduce exposure to the lowest achievable level even if that level is above the permissible exposure limit. Various arguments were made in support of this position. One participant pointed out that, where the controls will not reduce exposures sufficiently, respirators will have to be used anyway. This employer suggested that OSHA mandate the continued search for controls which are sufficient to reduce employee exposure, but allow employers to select any appropriate method of reducing exposures (Com. 43). As was pointed out in the benzene hearing (Ex. 59, p. 12), as well as in other OSHA rulemaking proceedings, respirators are the least satisfactory means of control because of difficulties inherent in their design and use. Respirators are capable of providing good protection only if they are properly selected for the types and concentrations of airborne concentrations present, properly fitted and refitted to the employee, worn by the employee, and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. Consequently, the protection of employees by respirators is not always effective and is, therefore, permitted only in certain specified circumstances. For example, proper facial fit, is essential but, due to variations in fit, individual facial dimensions and the limited range of the facepiece configurations, such fit is difficult to achieve. (Tr. 332-335) Often the work involved is strenuous and the increased breathing resistance of the respirator reduces their acceptability to employees. Safety problems presented by respirators must also be considered. Respirators limit vision. Speech is also limited. Voice transmission through a respirator can be difficult, annoying and fatiguing. Movement of the jaw in speaking also causes leakage. Communication may make the difference between a safe efficient operation, on the one hand, and confusion and panic, especially in difficult and dangerous jobs, on the other hand. Moreover, skin irritation can result from wearing a respirator in hot, humid conditions and such irritation can cause considerable distress and disrupt work schedules. It is clear, therefore, that respirators cannot be considered as the primary means of employee health protection. Nevertheless, respirators do provide some protection and OSHA has concluded that under certain limited circumstances, where no alternatives are available, respirators may be used to reduce employee exposures.

Industry participants further argued against a system of priorities because of alleged unfeasibility of engineering controls. Most of these participants' objections to methods of compliance, however, lie in the area of economic rather than technological feasibility (Com. 49, p. 5; Com. 54, p. 2; Com. 73, p. 3). As discussed below, OSHA has determined that this standard is feasible and that the implementation of engineering and work practice controls is for the most part technologically feasible. However, OSHA realizes that, under some particular circumstances, engineering and work practice controls may not be technologically feasible in a particular work operation. Therefore, the standard explicitly recognizes that an employer may demonstrate the infeasibility of engineering and work practice controls as to one or more operations in a particular process, and in these circumstances use respirators to provide the required protection. The question of whether an employer has met its burden of establishing that engineering and work practice controls are infeasible in a particular work operation involves the consideration of many complex factors and a rational balance process. Factors such as levels of exposure, useful remaining life of the equipment and the effort made by the employer to implement such controls are relevant.

In addition to the obligation to institute engineering and work practice controls, except to the extent that such controls are not feasible, the final standard also requires that each employer establish and implement a plan, including schedules for reducing exposures to within the permissible exposure limit or to the greatest extent feasible, solely by engineering and work practice controls. These written plans must be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director. These plans must be reviewed and updated periodically to reflect the current status of exposure control. Some participants felt that the requirement for written plans was burdensome and unnecessary (Com. 45, 59). OSHA, however, views the requirement for written plans as an essential part of the compliance program since it will encourage employees to actually achieve the controls and also provide the necessary documentation to OSHA, employers and employees of the compliance methods chosen, the extent to which controls have been instituted and plans to institute further controls to achieve safe and healthful workplaces.

A compliance issue relating to the requirement for engineering controls and work practices in this final benzene standard involves the relationship of that requirement to the covered employers' legal obligation as to engineering controls under the prior

benzene standard (29 CFR 1910.1000, Table Z-2). The new standard, at paragraph (f)(1), requires the implementation of engineering controls and work practices. OSHA views the two standards as a continuum of enforceable obligations which have been crystallized in the standards promulgation. More specifically, in evaluating whether the employer has instituted controls, OSHA compliance personnel would consider not only the employer's performance under the new standard but also his prior obligation under its predecessor.

Respirator protection: paragraph (g). The final standard contains requirements for respiratory protection. The standard requires employers to provide and assure the use of respirators whenever the permissible exposure level is exceeded. Paragraph (g) makes clear, however, that respirators are only to be used when other means of control are not feasible, and that the use of respirators is not a substitute for engineering and work practice controls. The standard allows respirators to be used to achieve compliance with the permissible exposure levels only in certain specific situations. The reason for the limitations is that respirators are, as stated above, the least satisfactory means of exposure control.

The standard contains a respirator selection table to enable the employer to provide the type of respirator which affords the proper degree of protection. While the employer must select the appropriate respirator from the table for each work operation on the basis of the airborne concentrations of benzene, he may always select a respirator providing greater protection—that is, one prescribed for higher concentrations of benzene than present in his workplace. It should also be noted that OSHA does not anticipate, as previously suggested in the proposal, that a conflict between the respirator selection table of the benzene standard and that of the coke oven standard will arise. Industry date (Ex. 136, attach No. 2) indicates that benzene exposures at coke oven batteries are generally below 1 ppm and respiratory protection for benzene exposure will generally not be required.

The standard further requires that the employer select respirators from among those approved by NIOSH under 30 CFR Part 11. Participants pointed out (Com. 41; Tr. 752; TR 139) that, although the standard's respiratory selection table permits the use of chemical cartridge respirators for concentrations of 50 ppm or less, NIOSH does not approve chemical cartridge respirators for benzene. OSHA is well aware of the fact that NIOSH does not approve organic vapor cartridge or canister respirators for substances, such as benzene, with poor warning qualities and that such respirators do not generally have end-of-service life indicators (Tr. 140). The standard's requirement for NIOSH approval, however, is designed to assure that only devices approved and certified by NIOSH for use against organic vapors be used, notwithstanding the fact that such certification carries a stated or implied prohibition against the use of these devices for substances with poor warning properties. The alternative would be to chance employee protection by allowing use of non-approved devices, or to require supplied air respirators or self-contained breathing devices which in many cases would give rise to extreme operational difficulties (Tr. 142). Since organic vapor cartridge and canister respirators currently approved by NIOSH have been shown to be effective in absorbing benzene vapors, neither of these alternatives is necessary.

To compensate for the lack of adequate warning properties of these respirators, the standard requires frequent replacement of the cartridge or canisters (Tr. 140). The standard requires that the cartridges or canisters be changed at the end of their service life or the end of the shift in which they are first used, whichever comes first. Some participants objected to the requirement to replace air purifying canisters and cartridges at the end of the shift. They felt that it would lead to waste (Com. 40), would do little to encourage research and development of an end of service life indicator (Com. 41), and would be too frequent where benzene concentrations are low and cartridge life is long (Com. 65). Recommendations for longer periods varied (Com. 53; L.C. 3; L.C. 19; Com. 60). OSHA has considered these recommendations but has concluded that, in order to assure that employees receive the maximum protection from benzene vapors, cartridges or canisters must be changed at least at the end of each shift. Should NIOSH, at some later date, certify a benzene end of service life indicator, which demonstrates that the canister or cartridge is useful past the end of the shift, OSHA would allow the cartridge or canister to be used for the extended period. Accordingly, the final standard has been changed to make this clear and hence encourage research and development of an end of service life indicator for benzene.

The standard further requires that the employer institute a respiratory protection program in accordance with 29 CFR 1910.134. This section contains basic requirements for proper selection, use, cleaning and maintenance of respirators. The employer is also required to assure that the respirator is properly fitted and to allow employees to wash their faces and respirator face pieces. In addition, paragraph (j)(i) of the standard requires that employees be properly trained in the use of respirators.

The standard requires that the employer shall provide respirators and other clothing and equipment required for protection from exposure to benzene at no cost to the employee. OSHA has allocated the costs of respirators and clothing and equipment required for protection from benzene exposure to the employer in order to effectuate the purposes of the Act. The employers' costs in providing respirators and protective equipment and clothing were considered in the economic assessment. This language clarifies OSHA's position which has long been implicit in health standard proceedings under section 6(b) of the Act.

Protective Clothing and Equipment: paragraph (h). The final standard retains the requirement that, where the employee is exposed to eye contact or repeated skin contact with benzene, the employer must provide and assure that employees wear the appropriate protective clothing and equipment. This requirement compels employers to furnish, where necessary, such items as goggles, face shields or gloves, or footwear.

The available scientific evidence on the intact and unbroken skin has been discussed above under Dermal and Eye Exposure Limits. Although the evidence on skin absorption of benzene is inconclusive, it is an "undisputed assumption" that the penetration of any benzene molecule will be greater through damaged skin (Tr. 2469-70). The record evidence also indicates that there are situations where employees are immersed or drenched with benzene liquids (Tr. 289, 292, 299). Liquid benzene on the skin may cause erythemia and blistering, and dry scaly dermatitis may develop on prolonged or repeated exposure (Ex. 2-3). Burns may occur from benzene spills (Tr. 292). One purpose of the protective clothing and equipment requirement is to protect employees from dermatitis and burns. Additionally, since benzene is a carcinogen and since breaks in skin surfaces commonly occur, OSHA has concluded that it is necessary to require personal protective clothing and equipment although the full effect of liquid benzene on the eye and the skin is as yet unknown. To do otherwise would be to leave employees unprotected and expose them to what might ultimately be shown as a most serious hazard.

Few comments were received on the protective clothing and equipment requirements. Some participants indicated that they already provide such protection to their employees (L.C. 4). One participant suggested that the extent of body exposure, which would trigger the need for the protective clothing, be delineated in the stan-

dard. (Com. 55.) OSHA, however, believes that the likelihood of eye or repeated skin contact and the resultant need for protective clothing must be assessed on the basis of individual workplace operations. One comment objected to the need for protective clothing or equipment where 1 percent or less benzene is present in the liquid benzene. There is, however, nothing to indicate that such percentages would create a sufficiently reduced hazard to warrant total elimination of the requirement.

The final standard requires the use of "impermeable" protective clothing and equipment. This requirement was in the emergency temporary standard. The proposal, however, would have simply required "appropriate protective clothing and equipment." Where eye and skin protection are required, the protective clothing and equipment to be "appropriate" must not allow liquid benzene to reach the eyes or skin. To make this clear, OSHA has adopted the language of the emergency temporary standard. The impermeable clothing must prevent all penetration of benzene. Thus, where impermeable gloves are used, liquid benzene should not seep through the cuff or any other opening in the glove. This could very well increase the hazard to the employee. It appears, on the basis of testimony from the industry expert witness, that, when a chemical substance on the skin is covered with a totally inclusive material, the rate of permeability of the substance through the skin is greatly increased (TR 2464; 2473).

Hygiene Facilities

Although normally required in carcinogen standards (See Coke Oven and Cancer Policy), the final benzene standard does not contain any requirement for hygiene facilities, such as waste disposal, housekeeping, showers, change rooms, or laundering of clothing.

The question of what, if any, hygiene facilities should be included in the final standard was at issue in the benzene rulemaking proceeding. The most common view of participants in that proceeding was that hygiene facilities were not necessary because of the volatility of benzene (L.C. 19). Almost all participants felt that no hazard would be created by the absence of hygiene facilities. One witness, however, testified that, in his opinion, the wife of a benzene exposed employee, who laundered her husband's work clothes daily died from benzene induced leukemia (Tr. 314). Unfortunately, no further information concerning this case was furnished. OSHA, consequently, finds that the record does not establish the need for a requirement for hygiene facilities.

Medical surveillance: paragraph (i). This standard requires that employers make available a medical surveillence program for those workers who are exposed to benzene at or above the action level of 0.5 ppm TWA. In addition, the regulation contains an emergency provision for the biological monitoring of employees exposed to a massive release of benzene.

Evidence contained in the record clearly indicates that a medical surveillence program is an appropriate measure. Hematologists, company physicians and other participants have recommended the inclusion of a medical surveillence provision in the final standard (Ex. 106; P.C. 30; Ex. 211; Ex. 17, Ex. 179, Bommarito, Tr. 3382). Also, a review of the record discloses that it is a current commmon practice of many industries to routinely examine their employees for evidence of benzene toxicity. (e.g. Wodka, Tr. 1263; Com. 26; Joyner, Tr. 2286; Dow, Tr. 2967, 3021; Ex. 77H.)

Section 6(b)(7) of the Act requires that employers make available medical examinations to ascertain whether the health of workers is adversely affected by exposure to toxic substances, where appropriate. The requirements contained in this regulation are designed to detect changes in the hematopoietic system resulting from chronic exposures to benzene which may be manifested in a range of blood disorders, including leukemia.

It is widely recognized that the major target organ in chronic benzene toxicity is the hematopoietic system, especially the bone marrow. This system has the attribute that a sample of the peripheral blood offers a unique biological "window" on the functioning and health of this system, providing much direct visual information not readily available for other organs or systems.

It is OSHA's view that a medical surveillance program directed toward the early detection of hematopoietic dysfunction by examination of peripheral blood samples is an appropriate measure. This determination receives support from: (1) Studies showing that early blood dyscrasias have been detected in workforces screened by laboratory tests (and often in workers displaying no obvious physical symptomatology) (Greenburg, Ex. 2-8, p. 419; Savilahti, Ex. 2-95, p. 1; Goldstein, Ex. 43B, p. 138); and (2) that even in cases of acute myelogenous leukemia, a period of remission, unfortumately brief, may be effected in a substantial proportion of those afflicted with this fatal disease by appropriate treatment. (ORC/Jandl, P.C. 34, p. 73-74). OSHA's decision is also supported by evidence that some cases of benzene-induced blood disorders may be reversed upon cessation of exposure and by appropriate treatment. (ORC/Jandl, P.C. 34, p. 39).

The medical surveillance provision of the proposed standard was the object of much comment and testimony. For example, over 45 separate comments addressed this issue in prehearing submissions alone. Additionally, substantial testimony was adduced during the hearing, and additional views were submitted to OSHA in the form of post-hearing comments. These suggestions addressed both the content and frequency of the examinations as well as what information should be elicited from the medical/work history portion.

OSHA, in formulating the provisions of the medical surveillance section, was aware of several problems. While there is no disagreement that the blood tissues are the most important organ relative to chronic benzene toxicity, there are as yet no consistent patterns of abnormalities, especially at low exposure levels, and no specific pathognomonic tests of benzene toxicity (Rosen, PC 23A, p. 2). Compounding this problem is the fact that it is difficult to separate cases of early benzene hematoxicity from more common minor blood disorders (Goldstein, Tr. 354). Associated with the problems of exam content is one of testing frequency. There are simply no precise estimates of the time course of the various abnormalities to allow determination of optimal testing frequency. Opinions based upon the lifespan of the blood cells are equally inapplicable in determining the frequency of such exams (Battle, P.C. 26C). While realizing that the more frequent the exams the greater the probability of detecting blood disorders induced by benzene, OSHA is also aware of the practical considerations of a medical surveillance program. Unlike the coke oven standard which applies to a defined number of workers employed in well characterized work sites, benzene is a component (usually as a contaminant) of a wide variety of refined petroleum solvents and, therefore, some benzene exposure occurs in a myriad of work sites and work operations. OSHA also recognizes that to be effective a medical surveillance program must be acceptable to a majority of workers subjected to the examination, the tests must display a high degree of accuracy and reproducibility, and the program should be able to be performed in a routine manner without unduly taxing medical resources. Given the above facts, the prescribed medical surveillance program is designed to accommodate the purpose of detecting early blood disorders resulting from benzene exposure without being overly burdensome and unduly intrusive.

The medical surveillance program consists of three main elements: (1) An initial and periodic examination for all those employees exposed to airborne benzene concentrations at or above the action level, (2) evaluation of ab-

normal findings by a hematologist and, (3) a biological screen for workers who may have received excessive exposure as a result of an emergency.

Several commentators and hearing participants recommended to OSHA that the medical screening program should be, in some way, related to employee exposure, and several specifically suggested that an action level be utilized as the determining boundary. (Com. 10; Com. 21; Com. 26; Com. 36; Com. 46; Com. 47; Com. 53; Com. 70; Com. 72; Com. 76; L.C. 3; PC 36; AISI brief). Many others felt that routine medical surveillance applied to all workers exposed to benzene without regard to degree of exposure, as was specified in the proposed standard, was an excessive requirement (e.g. Ex. 6-36). OSHA has examined these analyses and, as a result, has significantly altered the content of the surveillance program in the final standard. Furthermore, it is OSHA's view that the requirements of the medical surveillance program cannot be left to discretion of the examining physician because some physicians may not be fully aware of the wide range of effects resulting from benzene exposure.

The final standard requires that employers must make available an initial and periodic examination to any worker exposed at or above the action level. While it is the Agency's position that there is no "safe" level for benzene exposure, OSHA believes that the vast majority of workers exposed below the action level will not manifest blood dyscrasias, while those at or above this value are at greater risk, the precise extent of which is unknown. The inclusion of an action level concept will therefore limit medical surveillance requirements for those employees as to whom the probability of identifying benzene-induced blood disorders is in all likelihood minimal, and will focus such efforts on a population at increased risk.

Initial Examination

The initial examination has two components: a medical/work history and a series of laboratory blood tests. This differs from the proposed standard which drew no distinctions between initial histories and examinations and subsequent ones. The final standard does, however, make such a distinction. The purpose of the history is to alert the physician to problems which may indicate an individual's increased sensitivity to benzene. The permanent standard requires the taking of a history with the data elements specified in the proposal.

Eli Lilly (Com. 28) and Dupont (Com. 46) generally agreed with the proposed history requirements, while Dow Chemical agreed with the intent, i.e., that a complete medical history with an emphasis on blood problems is an essential part of a benzene medical surveillance program. They felt, however, that the wording should be simplified so that the worker could supply the information him/herself with minimal professional assistance. (Ex. 154.) OSHA, recognizing the merits of this suggestion, has not chosen to mandate the precise wording of the history taken, but only to require that specific areas should be queried. The employer, therefore, has considerable latitude with respect to the actual format. Whether the employee answers the medical history or is questioned by a health professional is also left to the discretion of the employer. The standard does require, however, that all aspects of the medical surveillance program be under the supervision of a licensed physician.

One hematologist objected to the inclusion of questions pertaining to a family history of hematologic neoplasms, noting that there is little evidence associating these disorders with a predisposing increased sensitivity to benzene (ORC/Jandl P.C. 34, Add. 5, p. vii). Another hematologist also criticized this provision on the basis that the information obtained was both unrealiable and of unknown relevance to benzene toxicity (P.C. 26C). Jandl also stated that genetically related hemoglobin alterations (hemoglobinopathies) are not highly relevant and are therefore of no predictive value (ORC/Jandl, P.C. 34). OSHA agrees that there is no known or even suspected association of benzene-induced blood dyscrasias with some hemoglobinopathies such as sickle cell anemia. However, Aksoy has reported findings that individuals with thalessemia (another hemoglobin disorder) may be more sensitive to the hematotoxic effects of benzene (Ex. 44). (It is not clear from Aksoy's testimony whether or not thalassemias are at greater risk of developing leukemias resulting from benzene exposure.) Moreover, he also observed a familial link with leukemia resulting from benzene exposure. (Ex. 24). In view of Aksoy's findings, OSHA believes that it is appropriate that the questions in the medical history relating hemoglobinopathies and a family history of malignant blood diseases remain in the standard.

Battle recommended that the health history also include questions concerning possible exposure to marrow toxins, such as the use of insecticides and volatile cleaning agents in the home (P.C. 26C). Since exposure to these types of agents may have significant impact on the blood picture of examined workers, queries regarding exposure to other marrow toxins both in and outside of the work environment have been added to the history requirements.

The initial laboratory examination requires that a series of classical blood tests and also measurements of serum bilirubin and reticulocyte count be performed. As noted, there is no consistent pattern of blood abnormalities resulting from benzene exposure. Various investigations claim that the earliest sign of benzene hematotoxicity is anemia or leukopenia, or changes in red cell indices. Some believe that red cell enlargement (macrocytosis) (Goldstein, Ex. 75; Goldwater, Ex. 140) or an absolute lymphopenia (Goldstein) may be suggestive of early marrow damage. (Occasional observations of a paradoxical hypercellularity in response to benzene exposure have been reported, e.g., by Aksoy; however, the basic hematological workup should detect this particular response).

An examination of the record demonstrates that there is general agreement that the following laboratory hematological tests should be part of an initial or baseline examination:

(a) Red Cell count
(b) White Cell count
(c) Hematocrit
(d) Hemoglobin
(e) MCV—(mean corpuscular volume)
(f) MCH—(mean corpuscular hemoglobin)
(g) MCHC—(mean cell hemoglobin concentration)

These tests are routinely performed in most blood examinations; they provide basic information about all three blood cell lines. The normal values are well known, and the tests are usually automated with the attendant benefits of being highly reproducible and accurate.

Differential counts of white blood cells, also required by the standard, are not amenable to automation and are therefore performed manually under microscopic examination by trained technicians. Battle commented that white blood cell counts are no longer performed on a routine basis in his clinic and that such an assay is usually only performed in response to abnormal cell counts (P.C. 26C). However, other commentators have recommended the inclusion of a differential count as part of a basic hematologic examination (both the initial and interval tests) (ORC/Jandl, P.C. 34, pp. 46-51, Goldstein Ex. 75). In addition to providing information on the relative number of various white cell types, the differential count provides an opportunity to observe aberrant cellular morphology and to note any unusual proportions of immature cells. Jandl feels that scanning of the slide by a trained technician for these types of findings is of the utmost importance (ORC/Jandl, P.C. 34, p. 45). For the above reasons, a differential count is a required part of the laboratory examination. In addition to the basic laboratory tests, serum bilirubin and reticulocyte counts must also be done in the initial laboratory exam. These tests may provide information indicative of

hemolytic states and other abnormalities. Because of the non-specificity of these two assays relative to benzene toxicity, the time-consuming nature and instability of the reticulocyte preparations, these particular tests were the object of much comment and criticism. Several commentators stated that although these tests were of little value on a routine basis, they should be made part of a preplacement or baseline exam (Com. 28, 72). Based on a review of this issue, OSHA believes that these two particular blood examinations should be included as a part of the initial laboratory tests only, to provide a more comprehensive picture of a worker's hematological profile, for possible later comparative purposes.

Several hematologists stressed the importance of obtaining pre-exposure data as a baseline against which latter comparisons could be made (ORC/Jandl, P.C. 34, p. 36; Battle, P.C. 26C; Goldstein Ex. 75, p. 5). The initial exam requirement of the standard applies to both employees already exposed to benzene at or above the action level as well as to new or reassigned employees who may be exposed at or above the action level. In the first case, the blood data obtained is not, of course, a true non-exposed baseline, but may be useful at a later date should significant changes in blood values occur. In addition, since the standard requires that an initial laboratory exam be performed for all new or reassigned employees prior to their actual exposure to benzene at or above the action level, pre-exposure baseline data will gradually become increasingly available in the years subsequent to promulgation of this standard.

As an aid to physicians for comparing the results of the most recent blood testing with early data, the recordkeeping paragraph requires that, at the completion of the differential count, the slide of a peripheral blood smear be made permanent and stored for possible future reference. Retention of the slide allows the examining physician to directly compare the most recent findings with earlier ones, especially with respect to possible changes in morphology of the blood cells; counting data alone would not permit this type of comparison.

Doc Chemical suggested that kidney and liver function tests should be performed as a part of the preplacement examination (Tr. 2967). OSHA recognizes that these laboratory examinations may identify conditions indicative of an impaired ability to detoxify benzene. However, given the low permissible exposure limit mandated by this standard, OSHA concluded that requirement of these tests would be excessively burdensome. In this regard, Goldstein testified that he saw no value to incorporate these tests (Tr. 380).

Periodic Examination

The medical surveillance section requires that a brief updated history be taken semiannally at the time of one of the blood examinations. Battle suggested that such a history include queries as to exposure to drugs or chemicals as well as recent illnesses since the last history (P.C. 26C). Because these agents may act to adversely affect the hematopoietic system and may be reflected in the blood picture, OSHA agrees with these particular suggestions and has incorporated all of them into the requirements for the interval history.

The periodic laboratory tests are similar to those specified for the initial exam, except that serum bilirubin and reticulocyte assays are deleted since, as stated above, the two assays are required only in establishing a baseline. Comments received by OSHA concerning the frequency of interval blood examination ranged from quarterly (ORC, P.C. 34, p. 11; Tr. 3382, Tr. 270) to 3 times a year (Com. 28; Tr. 3328; Battle, P.C. 26C), semiannually. (Tr. 3138) to those who felt the frequency should in some manner vary according to the exposure level (e.g., Tr. 2965, 6-10, 6-37, 6-47, 6-64, 6-76, 41-3, 41-19). Dow expressed the view that the frequency should be the decision of the responsible physician and related to the medical condition of the employee and the environmental control of the specific work area (Tr. 2965). As detailed previously, there is insufficient information in the record to allow a precise determination of optimum testing frequency. No completely reliable information exists on the number of months which elapse between the first laboratory signs of a blood disorder and the onset of clinical disease or what effect a particular time delay has on therapeutic outcome. There is no reason for casualness about the testing frequency though, since even if a blood change were to progress steadily downhill, early detection and treatment may provide substantial benefit. It is OSHA's judgement, following examination of the various options available, that a six month interval between routine blood examinations is appropriate.

The standard contains a provision, applicable to both the initial, periodic and emergency exams, requiring that employees' abnormal test results must be referred to a hematologist for further evaluation should certain specified warning signs appear. This provision, which was not a part of the proposal, is in response to recommendations that: (1) A hematologist be included in some manner in the medical surveillence program (ORC/Jandl, P.C. 34); (2) specific quantitative guidelines including ranges (Ex. 6-60) be given physicians and; (3) that additional laboratory tests should be given if an abnormal count becomes manifest or significant changes occur relative to baseline values (NPRA, Tr. 3325-3331; AISI, Tr. 3263-64; ARCO, P.C. 32C). With respect to item (1), an industry participant testified that it was already the practice at his company to refer workers to hematology specialists if blood abnormalities are discovered (Joyner, Tr. 2286-87), and Dow remarked that they discussed abnormal blood findings of workers with the hematologists (Tr. 3021). Also Arco commented that, if abnormal conditions arise among its employees exposed to benzene, follow-up examinations are given and medical treatment performed until blood tests reveal values within the normal range (P.C. 32C). Also, Dow disclosed that, for its imployee exposed to benzene, an increased medical surveillence program would result if conditions such as an undiagnosed anemia or leukocytosis were detected (Tr. 2984-85). Sakol has noted that ineffective and inappropriate medical treatment was given to workers apparently suffering hematological disorders from benzene exposure which ultimately evolved into a frank leukemia (Tr. 303). This incident further illustrates the need for a specialist's evaluation, if abnormalities are detected.

Again it should be emphasized that the question of what constitutes the earliest laboratory evidence of chronic benzene toxicity is not known with certainty (ORC/Battle, P.C. 26C, p. 3). It is known that the level of all 3 blood cell lines may be variously affected by exposure. However, examination of the benzene literature reveals that the hematological boundaries of what is considered "normal" have varied. More recent tabulation of normal *ranges* are those published by NIOSH (Ex. 2-2, p. 135): Wintrobe (Ex. 2-107, p. 1791, 1794, 1795) and those submitted by Jandl (ORC/Jandl, PC 34, p. 29). The normal range of hematological values presented generally agree quite well, especially those given by Jandl and Wintrobe. It is OSHA's conclusion that laboratory findings beyond these ranges must require additional evaluation by a blood specialist. In specifying the values beyond which findings are considered abnormal, OSHA utilized the values in the above citations to yield the widest range (often the range limits do not exactly coincide) in order to minimize the burden on the employer in borderline cases.

However, as illustrated by Goldstein, it may be possible for some individuals to experience a significant hematological response to benzene exposure and yet exhibit blood values within the range normal for the population as a whole (Goldstein, Tr. 356). To identify such workers for referral to a hema-

tologist, the standard also includes as a trigger, an allowable deviation figure for certain indicies, relative to an earlier determined value. The advantage of this approach is that the individual acts as his own control. As early as 1926, Greenberg in recommending criteria for exclusion of workers from further benzene exposure, utilized as one of his criteria changes in the blood picture based on results from previous examination of individual employees. He recommended a determined value of a 25% decline in red and white cell levels. The red cell count, hemoglobin and platelet count are generally very stable indicies and usually do not vary in individual cases by more than ±10% from baseline values. OSHA believes that a deviation of ±15% or more in these indicies compared to the laboratory findings obtained in the most recent test is of sufficient concern to require the attention of a specialist. As white cell counts commonly exhibit greater variation, a percentage deviation trigger would be too restrictive and is therefore not included in the standard. In lieu of a percentage deviation, limits of normal ranges are prescribed.

Emergency Situations

The emergency medical surveillance provisions reflect OSHA's concern for those employees normally subject to low average exposures but who, because of equipment breakdown or other causes, may be exposed to massive doses of benzene. These workers may be at a relatively high risk for developing adverse hematological effects.

If a worker is exposed to a massive release of benzene, the employer must provide for each individual so exposed a urinary phenol assay at the end of the work shift in which the emergency occurred. If the results of such a test corrected to a specific gravity of 1.024 are less than 75 mg/l, no further testing is required. However, if a urinary phenol result is greater than 75 mg/l, indicating an average exposure above 10 ppm (Watts, Ex. 2-109), then a complete blood count including a differential count must be performed as soon as practicable.

If the red blood cell or platelet count or hemoglobin differ more than ±15% from the most recent prior exam's findings, the worker's test results shall be referred to a hematologist for additional evaluation. Also, if the levels of the three formed elements lie outside of the prescribed ranges further evaluation by a hematologist shall be required.

The use of a urinary phenol assay to determine whether additional tests are indicated for workers exposed to high concentrations of benzene is supported by evidence in the record. The Sun Oil Company reported that special urinary phenol screening tests are prescribed for all persons when 10 ppm exposure levels are suspected (Ex. 77F).

For all types of medical examinations, the employer is required to provide the physician with certain information. This information includes a copy of the regulation, a description of the affected employee's duties as they relate to the employee's exposure, the results of the employee's exposure measurement, if any, or the employee's anticipated or estimated exposure level, a description of any personal protective equipment used or to be used, and information from previous medical examinations of the affected employee to the extent that it is not readily available to the physician. The purpose in making this information available to the physician is to aid in the evaluation of the employee's fitness to work in areas in which the exposure is at or greater than the action level. It should be noted that the standard does not require that a copy of the regulation be given to the physician for each employee. One copy would be sufficient, provided the employer informs the physician which employees are covered by this standard. Information that relates to individual employees or categories of employees (such as the description of job duties) need be transmitted to the physician only once, unless, for example, the duties change. Exposure measurements will be cumulative so that the results of each monitoring since the last examination are to be sent to the physician. However, since sampling may be done on a representative basis, the language of the standard requires the physician to be given either the employee's actual exposure measurements, if available, or the estimated level.

Several criticisms and suggested changes, discussed below, were also received by OSHA in regard to paragraph (i)(6) of the proposed medical surveillance requirements. In the final standard, the employer is required to obtain a written opinion from the examining physician containing: the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at an increased risk of material impairment of health from exposure to benzene, the results of the medical tests performed, and any recommended limitations upon the employee's exposure to benzene and upon the use of protective clothing and equipment such as respirators. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure, and a copy of the opinion must be provided to the affected employee.

Dow Chemical expressed the opinion that the notification requirements were overly burdensome and that the physician should be required to notify the employer and the employee only for the following reasons: Evidence of benzene toxicity, recommended limitations on worker exposure to benzene for any reason, or a health condition that precludes the use of protective clothing and equipment. (Tr. 2966). The Rubber Manufacturer's Association offered the comment that the physician's written opinion should be supplied to the employee only if requested (Ex. 6-59, p. 5). One commentator cautioned that because of malpractice considerations, a physician might be reluctant to sign such an opinion (National Paint and Coatings Association, Inc. (NPCA, Ex. 41-14, p. 15). Also because of malpractice considerations, the American Iron and Steel Institute recommend that this section be deleted (P.C. 36, p. 109). ORC suggested language changes for this physician's opinion requirement (ORC, P.C. 34, p. 11, Ex. 6-76, p. 11). The NPCA also warned that unless the physician's opinion paragraph was altered, denial of clearance for many prospective employees may result (Ex. 41-14, p. 15). There was also comment concerning with whom the doctor's opinion should be shared. ORC felt that any medical findings or diagnoses should be kept strictly confidential between the worker and the examining physician (P.C. 34, p. 11; Com. 76). Finally, a suggestion was received from industry that paragraph (i)(6)(ii) which limits the physician's opinion to specific findings and diagnoses related only to occupational exposure should be deleted on the basis that the employer has a right to know if there are any reasons related to work or not, that might have an adverse effect upon an employee or may possibly jeopardize fellow workers. (American Coke and Coal Chemicals Institute, Ex. 176, p. 9).

The purpose in requiring that specific findings or diagnoses unrelated to occupatonal exposure not be included in the written opinion is to encourage employees to submit to medical examination by removing the fear that employers may find out information about their physical condition that has no relation to occupational exposures.

The purpose in requiring the examining physician to supply a written opinion containing the above mentioned analyses is to provide the employer with a medical basis to aid in the determination of initial placement and to provide information on a continuing basis concerning whether or not the worker is at increased risk as a result of his/her benzene exposure. Requiring that the opinion be in written form will serve as an objective check that the employers have actually had the benefit of the information

in making these determinations. Likewise, the requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the result of the medical exam and may take appropriate action. Comments suggesting that the physician's opinion be communicated only if there are problems or only upon request are not acceptable to OSHA on the basis that the employer has the ultimate responsibility to assure the protection of the worker's health. Where the findings are negative, transmittal of the doctor's opinion also provides necessary information to both parties that the employee's health has not been adversely affected and provides documentary evidence that the prescribed tests were performed and were evaluated.

Other aspects of paragraph (i) of the medical surveillance section are to be discussed under Recordkeeping, paragraph (l).

Mandatory Removal and Rate Retention

Among the issues in the benzene rulemaking were whether OSHA should include a mandatory removal requirement—that is, a provision prohibiting the exposure of an employee to benzene if the employee would be placed at increased risk of material impairment to health because of such exposure, and whether OSHA should include a rate retention provision—that is, a provision requiring the transfer of such employee to another job or providing that removal for medical reasons should not result in loss of earnings or seniority status to the affected employee. These issues, as OSHA has previously stated (41 FR 46780), are related and must be addressed together. Both employee and industry participants expressed their views as to several aspects of these issues in prehearing comments, in testimony during the hearing and in post hearing arguments. Subsequent to the close of the record in this proceeding, however, OSHA conducted an informal public hearing on mandatory removal and rate retention for workers exposed to lead as part of the rulemaking proceeding on lead. Consideration of the critical issue of medical removal protection is being undertaken for several pending standards together. Once this consideration is completed, OSHA will consider the extent to which the conclusions on medical removal protection are appropriate for benzene and will propose the inclusion of those provisions in the benzene standard. The final standard published today, therefore, does not address the issues of mandatory removal and medical removal protection.

Employee Information and Training: Paragraph (j). The standard requires each employer to provide training to each of his employees who is or may be exposed to benzene. The need to train employees was not disputed by participants in the rulemaking proceeding. Some comments, however, suggested limiting the training to certain employees. One industry comment requested that workers in closed system operations be excluded from training (Com. 47). Testimony at the hearing, however, revealed that leakages in closed systems are not unusual occurrences and that employee exposure during leaks can reach high levels. One comment suggested the exclusion of workers in open system operations where the benzene content is 1 percent or less (Com. 47). However, as stated above, it has been established that a consistent predictable relationship between the amount of benzene in a mixture and exposure levels does not exist and this suggestion has, therefore, been rejected. Another comment suggested the exclusion of laboratory personnel from training requirements on the ground that laboratory personnel have a good understanding of the hazardous nature of benzene (Com. 70). A laboratory technician, however, testified that during his six years working with many toxic chemicals, including benzene, he received no training (Tr. 3493) and indeed neither he nor his coworkers were aware of the fact that there was an OSHA standard limiting exposure to benzene (Tr. 3492). Information and training are essential for the protection of an employee. Each employee can do much to protect himself if he is fully informed of the hazards in his workplace and the protective equipment he should use. Furthermore, each employee, who is fully informed of the obligations which the standard imposes upon the employer, can determine if he is working in a safe and healthful environment. For the reasons stated herein, OSHA believes that training must be provided to all employees in workplaces where benzene is present.

A trade association, while not disputing the need for training, suggested that employee training not be included in the benzene standard but await development of a comprehensive employee information and training standard based on the report of the Advisory Committee on Hazardous Materials Labeling and/or NIOSH's criteria document entitled "A Recommended Standard * * *.

An Identification System for Occupationally Hazardous Materials" (L.C. 14). OSHA deems it necessary for the protection of the health of employees to include the training requirements in the benzene standard at this time.

The standard specifies the contents of the training program. The information which must be imparted to the employee must include the nature of benzene related health problems, the necessity for exposure control, and the purposes of medical surveillance and respiratory protections. No participants objected to any of these items. Two participants suggested that employees should also be trained in "early symptom diagnosis to detect acute leukemia" (Ex. Dow Venable statement, pg. 3; Tr. 3192; Ex. 154; Tr. 2963-3056). These participants, however, testified that the most common manifestations of acute leukemia are fatigue and nosebleeds and that these symptoms are not specific to acute leukemia (Tr. 3193).

The signs and symptoms of benzene-induced diseases are described in considerable detail in Appendix A and Appendix C. Both the proposed standard and the final standard specifically require that the employees be informed, among other things, of the information contained in Appendix A and Appendix C. (In this connection, the employee should be instructed to report promptly the development of any of these symptoms which could be attributed to benzene exposure.) In view of the requirement to include the information contained in the appendices as part of the training program, an additional requirement on early symptom diagnosis would be redundant. Similarly, since Appendix B details the volatility of benzene, OSHA has not adopted NIOSH's suggestion (Baier statement, Ex. 84A p. 11) that the standard further emphasize training on the flammability of benzene.

In addition to informing employees, the standard requires that the employer make available to his employees a copy of the standard and its appendices. This requirement is intended to assure that employees understand their rights and duties under the standard.

A public participant suggested that employers be required to hold classes for the training of each employee. (Ex. 183 p. 5) OSHA has not included any specific requirement to this effect in the final standard, preferring to leave the manner of training up to the individual employers. Some employers will need to train individuals on a one-to-one basis, depending on the number of employees at a particular workplace or involved in particular operations. Employers with a few employees may find it burdensome or disruptive of work schedules to conduct training in class sessions.

The employer is also required to provide, upon request, all materials related to the training program to the Secretary and the Director. This requirement is intended to provide an objective check of compliance with the content requirements of the training program.

The standard requires that training of employees be conducted within

ninety days of the effective date. Newly assigned employees must be trained at the time of initial assignment. The standard further requires that training be repeated annually. These requirements were not explicitly in the proposed standard; however, they are consistent with OSHA's policy on training (see, Coke Ovens Emissions Standard) and have been included in the final standard to assure that employees are trained promptly and receive continuing education essential to the protection of their health.

Signs and Labels: paragraph k. The requirements of the standard regarding the posting of warning signs and affixing caution labels remain primarily the same as those in the proposal with some difference in the legend of these signs and labels. These requirements are consistent with section 6(b)(7) of the Act which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Signs. The standard requires the posting of warning signs in regulated areas. Some industry comments objected to this requirement on the ground that the training requirements of the standard are sufficient for informing employees of the hazards of benzene (Com. 28). In light of the serious nature of the hazard of exposure to benzene, OSHA does not agree. Not every employee will have completed his training before entering an area of operation where the exposure to benzene is over the permissible exposure level. Moreover, even trained employees will need to be reminded of the locations and the dangers of entering these areas. Additionally, other workers, such as employees of independent maintenance contractors who are authorized to enter particular regulated areas, need to be warned of the hazard and reminded to use protective equipment. OSHA, therefore, believes that both signs and training are necessary to adequately apprise employees of the hazards of benzene.

Other comments requested that laboratories be exempted from the sign requirements (Com. 70) on the ground that laboratory personnel are familiar with the hazards (Com. 20) and because there are already too many other hazardous substances in these work places (Com. 28) for which signs are posted (Com. 37). One comment expressed the view that there is no hazard from exposure to benzene in laboratories or other physical areas where the content of benzene in the mixture used is small (Com. 63, 59) or where benzene is used infrequently (Com. 70). As stated above, there is no established consistent predictable relationship between the amount of benzene and the exposure level, nor does infrequency of use eliminate the hazard. Signs are required by the standard only in regulated areas where, by definition, the exposure is above the permissible exposure limit. Furthermore, as stated above, OSHA believes that training in hazards alone is not sufficent to inform employees of the potential health hazards of entering or working in a regulated area and the need for the use of protective equipment.

Since warning the employees is necessary, the standard explicitly provides that the employer must assure that nothing which detracts from the required information appears near or on the sign. Laboratory and other employers who have other signs posted in the regulated area, therefore, have the responsibility for meeting this requirement.

Another comment pointed out that signs would be required even where benzene was in a closed system regardless of lack of employee exposure (Com. 65). This comment appears to overlook the fact that signs would be required only in those areas where employee exposure is over the permissible exposure limit and that, if there is no benzene exposure from the closed system, no sign is required. This same comment suggested that signs would be required where benzene was in a sealed container. Since there is no exposure to employees when benzene is in sealed containers, the standard exempts sealed intact containers from all requirements but the labelling and training requirements; hence signs would not be required in areas where benzene is present solely in sealed intact containers. Another comment suggested elimination of sign posting requirements for gasoline products (Com. 55). Since benzene is present in gasoline there is, of course, a benzene hazard attendant to exposure to gasoline. However, sampling data indicates that exposure to benzene is usually below 1 ppm., which would, in such cases, obviate the need for signs.

The standard specifies the wording of the signs. The purpose of this provision is to assure that the proper warning is given to employees. Some participants suggested that the word "Cancer" be replaced by "Leukemia Suspect Agent" (AISI, Princ. Wit, Ex. 156. Tab I, p. 34; PC 36; AISI brief, p. 108; PC 35; MCA brief pp. 103-5, Com. 39). In view of the fact that it has been established that benzene actually induces leukemia, OSHA does not agree that "Leukemia Suspect Agent" adequately informs employees of the hazard. For the same reason, OSHA has not adopted the suggestion of another comment that the sign merely warn of the presence of breathing zone vapors which "may" be hazardous, the need to wear respirators and that unauthorized persons should stay out (Com. 69). One comment pointed out that the sign requirements do not warn of other serious health hazards that may result from exposure to benzene. Addition of the various other health hazards would increase the wording on the sign with the likely result of detracting from the cancer warning. The reference to the most serious hazard is, in OSHA's view, a sufficient alert to employees that entering the regulated area may be hazardous. Some comments objected to the use of the term "Cancer Hazard" (Com. 26) on the ground that it would only serve to unduly alarm employees (Com. 28, 50). One comment suggested "Cancer Suspect Agent" be used to conform with 29 CFR 1910.1017 which regulates occupational exposures to vinyl chloride. Since exposure to benzene creates an increased risk of leukemia, and since leukemia is cancer of the blood, OSHA does not believe that the hazard is overstated by the use of the term "Cancer Hazard." Nor has OSHA adopted the suggestion that the word "Leukemia" replace the word "Cancer" (Com. 76). While the term "Leukemia" is more specific of the nature of the hazard, "Cancer" is the more familiar term and thus more readily alerts the employee.

Another comment (Com. 69) suggested that the word "Caution" be substituted for "Danger" to conform to 29 CFR 1910.145 (c)(1) and (2) which provide that danger signs should be used only where an immediate hazard exists, and caution signs used only to warn against potential hazards or to caution against unsafe practices. The suggestion was based on the view that OSHA failed to show that there exists a cause-effect relationship between employee exposure to benzene concentrations below 10 ppm. In view of the epidemiological evidence of the human carcinogenicity of benzene, OSHA feels that the use of the word "Danger" is appropriate. Furthermore, the word "Danger" is used to attract the attention of workers, to alert workers to the fact that they are in a hazardous area, i.e., an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message to follow. The use of the word danger is consistent with the Coke Ovens Emissions Standard and other recent health standards.

Two comments objected to the legend "Respirator Required" pointing out that respirators are not always required in regulated areas. The reason given was that, although the concentration within a regulated area will be above 1 ppm, the employee would not have to use a respirator if his 8-hour TWA were below 1 ppm and his 15 minute ceiling is below 5 ppm (Com. 46, 59). OSHA recognizes that some employees entering regulated areas may not be exposed above the permis-

sible exposure limit. It is likely, however, that there will be many employees who work in the regulated areas for such periods of time or at such levels of exposure that they would without respirators be exposed to well above the permissible exposure limit. For this latter group, respirators would be required to reduce their exposure levels. To assure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators. Moreover, since even persons who are in a regulated area occasionally and are not exposed over the permissible exposure limits may face an increased risk of leukemia, OSHA does not believe that the respirator warning is such an overstatement as to necessitate elimination of that warning from the sign.

One comment pointed out that the warning sign ignores the flammability of benzene (Com. 50). NIOSH also recommended that the potential danger for fire be displayed on signs with equal prominence with the toxicological hazards. (Tr. 755) OSHA agrees. Benzene, as has been stated, is a highly flammable liquid. Accordingly, in the final standard, OSHA has added a requirement that the signs also contain the legend "Flammable—No Smoking" with equal prominence to the legend "Cancer Hazard."

Labels. The standard requires the use of caution labels on all containers of products containing any amount of benzene. This requirement imposes upon the employer the obligation to assure that all such containers within his workplace are at all times properly labeled. Some industry comments requested that OSHA define "container" (Com. 46, 55, 65) in terms of sizes and types of containers (Com. 53; Com. 72). Participants also appeared to be confused as to whether storage tanks, pipelines, tank cars and tank trucks are such containers as would be require labeling (Com. 60). The purpose of the labeling requirement is to assure that, wherever benzene is present in any quantity, employees are apprised of the hazard. The size or type of the container or its use as a storage vessel is, therefore, not material to this objective. In imposing the labeling requirement, however, OSHA does not intend to include pipelines, or to include trucks or other vessels transporting benzene products in sealed containers. At many points of pipelines, there is no employee exposure nor can the point at which benzene enters a product stream often be determined. Benzene in liquid mixtures, other than in gasoline, is often transported in closed containers, in which case labeling of the container is sufficient without a need for labeling the transport vehicle. Where benzene products not in containers are transported in barges or other tank vessels, such as tankers and tank trucks, it is, of course, necessary that the vessel be labeled. With regard to gasoline, the standard does not cover activities past the bulk terminal and, therefore, gasoline trucks would not require labelling. In view of the above, the standard specifically excludes from the labeling requirements pipelines and any transport vessels or vehicles where the benzene product is transported in sealed containers.

Some participants suggested that the labeling requirements apply only to containers which have liquids with greater than 1% benzene (Com. 53, 72). It was also suggested that labels be affixed only to containers from which exposure to benzene levels above the permissible exposure limit might be reasonably expected to occur so as to exclude a requirement to label finished products which might contain trace amounts of benzene (Com. 59). Since there is no known safe level of exposure to benzene, OSHA feels that, for employees to be adequately apprised of the hazard, all containers must be labeled in the same manner.

The standard requires that the caution labels remain affixed when benzene products leave the employer's workplace. Some comments questioned OSHA's jurisdiction to impose such a requirement (Com. 50, 55, 59). The purpose of this requirement is to assure that all employees, not only those of a particular employer, are apprised of the hazardous nature of benzene exposure. It is OSHA's view that informing employees of the hazards to which they are exposed is an important element in reducing occupational disease and injury and one of the significant purposes of the Occupational Safety and Health Act. Section 6(b)(7) of the Act, which explicitly provides for regulation requiring the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed, is broadly drawn. This section does not limit the employer's obligation of informing employees of hazardous conditions to the employer's own employee. When an employer manufactures, formulates or sells a product containing a toxic substance, that employer is exposing not only his own employees but also the employees of other employers involved in handling, transporting or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulator or seller will in many cases be the only employer capable, through his unique knowledge, of providing the information needed for protection of employees. A narrower reading of the statutory authority would defeat the protective purposes of the Act by withholding from employees down the line who come into any contact with the product, adequate information as to the hazard. Furthermore, the use of the labels will alert other employers, who utilize or handle the product and who would not otherwise know of the presence of benzene in their workplace, of their obligation to comply with the standard. OSHA, therefore, feels that this requirement is necessary and appropriate to effectuate the purposes of the Act.

The standard prescribes the legend that must be included on the label. This is to assure that employees are alerted to the fact that they are handling benzene and to the hazard involved. The record evidence establishes that a variety of code names have been used for benzene (Ex 61, Sakol) and that employers (Tr. 3383; 3516), workers (Tr. 3402) and physicians (Tr. 305-6) often do not know that the product contains benzene. Some participants suggested that labels state the percentage of benzene in the product (Com. 58, 21, 59). In order to keep the label information to a minimum and since there is no consistent predictable relationship between the amount of benzene in the product and the percentage level, the final standard does not require any such statement on the label.

Recordkeeping and reporting. The provisions for recordkeeping, reporting, availability of records and the transfer of records are similar to those in the proposal. Such changes as have been made in the final standard are in response to the request of public participants that OSHA reduce the burden imposed by these types of requirements. These provisions implement the requirements of section 8(c)(1) and (3) of the Act, and are consistent with OSHA's general policy concerning records and reports.

Records: paragraph (1) The standard requires a limited amount of recordkeeping. Employers must maintain exposure measurement records and medical records.

The need for keeping these records was generally accepted by the participants in the benzene rulemaking. The common purposes of these recordkeeping requirements is to assure the employer's compliance with the control measures designed for the protection of his employees, and to collect data vital to epidemiological and diagnostic investigations in order to resolve such questions as dose-response relationships in blood diseases caused by exposure to benzene. Furthermore, these records are useful for the employer by enabling him to identify areas of his operations where there is or may be a problem. Exposure measurement records assist in pinpointing those processes or operations which require additional efforts to reduce exposure to benzene. Medical records provide an

awareness of the incidence of industrial illness in the employer's establishment and assist the employer to focus on any aspect of his operation which may materially impair the health of his employees. The required records are also useful to the employee: Exposure records assure employees that their exposure to benzene is being monitored and also inform them of the hazards to which they are exposed; medical records assist their examining physician to accurately diagnose and treat any health problem and assure proper evaluation of their health.

The standard specifies the information which must be included in the record. The exposure measurement record must include information which accurately reflects the exposure of each individual employee. The medical record must include the work history of each individual employee and information accurately reflecting his health. A few participants disputed the need for the content of some of these records. One comment suggested deletion of the requirement in paragraph (l)(1)(i)(b) to include as part of the exposure record a description of sampling on the ground that it is the same requirement as in paragraph (l)(1)(i)(a) for a description of the sampling procedure used to determine representative employee exposure. (Com. 76) This participant has misunderstood these requirements. The "description of sampling" in subparagraph (b) refers to the type of equipment used for collecting the concentrations of benzene, the rate at which these samples were collected and the minimum period during which the collection took place. The "sampling procedure" referred to in subparagraph (a) refers to the criteria or method used by the employer to determine that the samples he has taken are representative of the particular employee's exposure. Although these paragraphs are directed to different requirements, OSHA has eliminated from subparagraph (a) of this provision the word "sampling" in order to avoid such confusion on the part of other employers.

Another comment expressed the view that requiring employers to include in the record all of the information provided to the examining physician is an undue administrative burden (Com. 59). Where the information is communicated in writing to the doctor who will examine the employee, the employer can meet his requirement by simply retaining in his files a copy of this communication. Where, however, the information is not furnished in writing, it is essential to record it to assure that the examining physician has been advised of all the information needed for evaluation of the employee's health. Moreover, since this information includes exposure conditions and symptoms, the information is most useful not only to the current examining physician but also to a physician who years later evaluates the health of the employee. OSHA, therefore, has retained in the standard the requirement to record the information provided to the examining physician.

An industry comment pointed out that it is not necessary for the company physicians, who maintain the medical records on behalf of the employer, to retain a copy of the regulation and its appendices as part of the record of each individual employee, but that retention of one master copy in the files would be sufficient if there is a reference to it in each employee's file (Com. 46). OSHA agrees that retention of the regulation and appendices in each employee's file unnecessarily increases the space needed for the records and, accordingly, has given employers the option in the final standard of either including the regulation and appendices in each employee's file or of retaining a master copy of these documents and referencing them in each employee's medical file.

Some industry participants testified that their facilities would need additional record clerks to maintain the information in the required records (TR 3165-3171). In view of the reduction in the final standard of the number of employees for whom exposure and medical monitoring must be conducted and reduction of at the frequency rate suggested by the proposal, the need for additional recordkeeping personnel is significantly reduced. Furthermore, since the standard does not require the use of any particular form for maintaining the prescribed information, employers may incorporate these records into already existing recordkeeping systems, some of which are computerized, and thus further minimize the need for additional personnel.

The standard requires that the exposure measurement records and medical surveillance records be maintained by the employer for at least 40 years or for the duration of employment plus twenty years, whichever is longer. Several participants objected to the length of this retention period. One comment expressed the view that the retention period was unnecessarily burdensome where the only exposure to benzene is from liquid products containing small amounts of benzene (Com. 55). Both because there is no known safe level for exposure to benzene and because there is no direct linear correlation between the percentage of benzene in a liquid mixture and exposure levels, OSHA feels that there is no basis for different retention requirements based on the amount of benzene in liquids. Moreover, in view of the provision for an action level in the final standard, the number of exposure measurements and medical examinations which must be recorded will be greatly minimized where the small amounts of benzene actually do result in exposures below the action level.

Another comment suggested that the retention period for the medical surveillance records is unreasonably long (Com. 59). OSHA is aware of the burden of keeping both the medical and the exposure records for this length of time. However, OSHA feels that it is essential that the records be retained for this period. The record evidence establishes that the latency period for benzene induced leukemia is unknown (Ex. 2B-283, p. 4) and that, as in the case of other chemical carcinogens, the symptoms of carcinogenesis—in this case, benzene induced leukemia—may not appear for many years after the initial exposure (Tr. 385, 391, 410-11, 424). The retention period of forty years has, therefore, been selected to assure that the entire latency period would be covered. Furthermore, as stated in OSHA's standard for Coke Ovens Emissions (41 FR 46782), OSHA believes that it is essential to scientific investigations that exposure and medical records be maintained for the same length of time, and that the retention period for these records be at least forty years.

One comment suggested that independent contractors, who customarily hire employees only for temporary work at a particular facility, be allowed to send the medical records to the Director of NIOSH upon expiration of the employee's employment (Com. 63). As is noted below, it is OSHA's policy for all employers that the records be maintained at the place of employment so long as it is in existence.

The standard does not require that the employer, on any regular basis, send copies of his records to OSHA. The employer is, however, required upon request to make the records available for examination and copying to designated representatives of OSHA and NIOSH. This requirement is necessary both for compliance purposes and for scientific investigations. Records of required exposure monitoring are, in addition, to be made available, for examination and copying, to current employees and their representatives; and exposure monitoring records indicating their own exposure must be made available to former employees or their designated representatives. One participant suggested deletion of the reference to the term "or their designated representative" (Com. 48) thus restricting access to appropriate exposure records only to the current or former employee himself. OSHA is of the view that denying access to the re-

cords of individual exposure by designated representatives could result in a denial of access to the information by the employee where he is incapacitated and unable to inspect the records or simply not able to understand them. This would defeat the purpose of the availability provision which is to assure current employees that their exposure is properly monitored and assure former employees of access to information necessary for the continued protection of their health. Furthermore, the Act recognizes (sections 2(b)(13); 8(c)(3); 8(f)(1)) the legitimate role of employee representatives in occupational safety and health. One industry comment suggested that employee representatives be formally designated in writing and that access to records also be requested in writing (Com. 15). OSHA does not deem it necessary to include such a requirement in the standard, but employers may establish procedures for access to records so long as the procedures do not restrict the employees' and former employees' to access.

The standard also requires that medical records also be made available, upon request, for examination and copying to the designated physicians or representative of both current and former employees. Some comments questioned the fact that the standard enables not only the employer but also the employee and his representative and OSHA and NIOSH to have access to medical records without specifying confidentiality or otherwise limiting circulation of the information (Com. 26, 48). OSHA recognizes that a physician's records may contain a wide range of personal and medical information deemed to be confidential or private. For this reason, the standard limits the contents of the medical record to such information as is related to benzene exposure. Indeed, the standard requires in paragraph (i) (6) (ii) that the employer advise the physician that the physician's opinion, which becomes a part of the medical record, should not reveal findings or diagnoses unrelated to occupational exposure. The need of the employer, the employee and OSHA and NIOSH to have access to this information has already been thoroughly discussed. Disclosure of the information to other persons is, of course, subject to protective requirements of any applicable laws or regulations.

To assure that the records will be preserved for the required retention period of forty years, the standard requires an employer, who ceases to do business, to transfer his records to his successor and, in the event that there is no successor, to transfer the records to the Director of NIOSH. One industry comment suggested that this section be deleted. (Com. 59). Allowing employers to dispose, at will, of the records of exposure measurements and medical surveillance would result, more often than not, in destruction of these records thus depriving employees of information necessary for evaluation of their health, as well as depriving NIOSH of information valuable to its scientific investigations.

Another participant suggested elimination of the requirement that the records be transferred to NIOSH by registered mail. (Com. 68). OSHA has adopted this suggestion and the permanent standard eliminates the requirement to use registered mail.

Reports. Paragraphs (d)(3), (e)(5), (f)(2), (i)(4)(i). The standard imposes notification requirements upon employers. This requirement is discussed above under *Regulated Areas.*

The standard also obligates the employer to give certain information to employees. The employer must notify each employee of the exposure measurement representative of his exposure. This notification must be made regardless of what the exposure level of the employee is. Two comments suggested that availability of exposure records was sufficient to inform employees of the results of their monitoring (Com. 46 Com. 53). Several comments suggested that the notification be required only where the employees' exposure is above the permissible exposure level (Com. 10, 15, 21, 41, 46, 53, 59) and that exposures below the permissible level be available to the employee upon request (Com. 10). OSHA believes that, consistent with section 8(c)(3) of the Act, every employee has the right to know what his exposure level is and whether it is above or below the permissible exposure level. Moreover, since the permissible exposure level is a feasibility level and not a "safe" level, the employee must know, for proper evaluation of his health by a physician in the present and future, the level of benzene to which he is exposed. Accordingly, the suggestions to modify the employee notification requirements have not been adopted.

The standard further requires that, where the employee's exposure is over the permissible exposure level, the employer must also state in the notification what corrective action the employer is going to take to reduce the exposure level. This is necessary to assure employees that the employer is making every effort to furnish them with a safe and healthful work environment, and implements section 8(c)(3) of the Act.

Notifications to employees of their exposure levels must be made in writing. Several comments objected to this requirement. Some comments suggested that the employer be permitted to notify employees by posting of a notice on the workplace bulletin board (Com. 15, 49, 59), thus relieving the employer of the burden of notifying each and every employee. It is OSHA's view that direct notification to each employee is necessary in order to assure that the employee, as required by section 8(c)(3) of the Act, is apprised of all hazards to which the employee is exposed.

The standard further requires that the notification be within five working days after receipt of the employer's measurement results. Several industry comments requested a change in the five day requirement so as to allow additional time for employers to comply. (Com. 47, 49, 54, 59). OSHA feels that, under ordinary circumstances, the five day limit fulfills the statutory requirement for promptness (section 8(c)(3)) yet allows employers sufficient time for the written notification.

The standard further obligates the employer to provide the employee with a copy of the examining physician's written opinion. One industry comment pointed out the large volume of letters per year which this notification would entail (Com. 53). However, in view of the necessity for each employee to have an evaluation of his health, OSHA is of the view that furnishing each employee with a copy of the physician's letter is not unreasonably burdensome.

Written compliance programs are also required by the standard. These are discussed above under *Methods of Compliance.* The employer is required to submit his compliance program, on request, to OSHA and NIOSH. Additionally, he must make this program available at the worksite for examination by OSHA and NIOSH and by his employees or their authorized representatives. One participant suggested that employers be required to give to each employee a notice of availability of the compliance program rather than merely making it available to the employee or his representative. OSHA feels that this would place an unnecessary burden upon the employer, and has not incorporated the suggestion.

Observation of monitoring: paragraph (m). The final standard requires that the employer provide affected employees or their designated representatives with an opportunity to observe the measuring of employee exposures. This opportunity is specifically required by section 8(c)(3) of the Act. The standard also sets forth certain procedures which must be complied with in connection with the observation of the monitoring. These procedures are designed to assure that the right to observe is meaningful and that the health and safety of the observer is protected during the observation.

A few industry participants requested that the observation of monitoring provision be deleted from the standard (Com. 65). Union participants objected

to any limitations on this requirement (Grospiron statement, Ex. 11.A, p. 12). The arguments by industry were several: (1) The requirement fails to limit the number of employees who can observe the monitoring; (2) it increases the employer's costs of monitoring; (3) employees lose time from their jobs; (4) it exposes employees to additional hazards; (5) it increases the liability potential for non-employees who are injured while observing; and (6) will result in labor/management confrontations (Com. 65, 70: L.C. 4). In view of the statutory mandate that "regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring," OSHA has not adopted the suggestions to delete this provision.

One comment suggested that a one-time limit on observation of monitoring be established for each employee (Com. 60). OSHA has not adopted this suggestion since the statute does not impose any such limit and it does not appear to be reasonable. For example, a requirement to this effect would prohibit an employee or his representative who has observed the original monitoring to observe the redetermination of exposure which is required by the standard after a process or control change.

Effective Date

In order to assure that affected employers and employees will be informed of the existence of the provisions and terms of this standard, and that employers and employees are given an opportunity to familiarize themselves with any new requirements, the effective date of this standard will be March 13, 1978. Until such date, 29 CFR 1910.1000. Table Z–2 will continue to apply to those operations covered by the new 29 CFR 1910.1028. Subsequent to that date, 29 CFR 1910.1000, Table Z–2 will continue to apply to all operations exempted under the new 29 CFR 1910.1028.

Appendices

Three appendices have been included in this permanent standard. These appendices have been included primarily for information purposes. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standard or as detracting from an obligation which the standard does impose.

The information contained in Appendices A and B is designed to aid the employer is complying with requirements of the standard. The information in Appendix C primarily provides information needed by the physician to evaluate the results of the medical examination. Appendix C also lists other types of examinations, not required by the standard, which may help the physician in making an accurate assessment as to whether continued exposure to benzene will place the employee at an increased risk. It should be noted that paragraph (j)(1)(i) and (iv) specifically require that the information contained in Appendix A and C be provided to employees as part of their information and training program.

Some suggestions were made by participants regarding the contents of these appendices. One participant suggested that Appendix A, Part III–A include the requirement as to frequency of change of respirator cartridges and canisters (Com. 8). OSHA has not adopted this suggestion since the requirement is clearly set forth in the standard, and the employer is required as part of the training program to give each employee a copy of the standard. Another participant (Com. 59) suggested that Appendix A, I, B2 state that eye contact and repeated skin contact "be avoided" instead of "prohibited." OASH does not agree since the standard prohibits such contact. This same participant suggested that the last sentence of Appendix A, IV, A be changed to indicate that medical assistance should be sought only if irritation of eye or face persists. This limitation has not been added for the reason that OSHA feels that the more conservative advice imparted by the proposed paragraph better alerts the employees to the possible hazards of this type of exposure. The third suggestion of this participant was that Appendix A state that "medical assistance" be sought rather than that "a doctor" be called when large quantities of benzene are breathed. A modification of this suggestion has been adopted and it is now recommended that medical assistance or a doctor be called for as soon as possible.

VII. Authority

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, pursuant to sections 4(b)(2), 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 1596, 1596, 29 U.S.C. 653, 655, 657), the specific statutes referred to in section 4(b)(2), Secretary of Labor's Order No. 8–76 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations, is hereby amended by deleting the emergency temporary standard for occupational exposure to benzene at § 1910.1028 and adding a new permanent standard for occupational exposure to benzene as § 1910.1028, and by amending Table Z–2 of § 1910.1000. In addition, pursuant to section 4(b)(2) of the Act (84 Stat. 1592; 29 U.S.C. 653), OSHA has determined that this new standard in § 1910.1028 is more effective than the corresponding standards now in Subpart B of Part 1910, and in Parts 1915, 1916, 1917, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards are superseded by this new § 1910.1028. This determination, and the application of the new standard to the maritime and construction industries, are implemented by adding a new paragraph (c) to § 1910.19 and by revoking § 1910.20.

Signed at Washington, D.C., this 31st day of January, 1978. These amendments are effective on March 13, 1978.

Eula Bingham,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

1. A new paragraph (c) is added to § 1910.19, to read as follows:

§ 1910.19 *Special provisions for air contaminants.*

* * * * *

(c) Section 1910.1028 shall apply to the exposure of every employee to benzene in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or § 1910.16, in lieu of any different standard on exposure to benzene which would otherwise be applicable by virtue of any of those sections.

§ 1910.20 [Revoked]

2. Section 1910.20 is revoked.

§ 1910.1000 [Amended]

3. Table Z-2 of § 1910.1000 is amended by adding a footnote following the words "Benzene (Z37.40-1969)," and by adding the following below Table Z-2:

4. Section 1910.1028 is revised to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* (1) This section applies to each place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled, or used.

(2) This section does not apply to:

(i) The storage, transportation, distribution, dispensing, sale or use as fuel of gasoline, motor fuels, or other fuels subsequent to discharge from bulk terminals; or

[1] Occupational exposures to benzene are subject to the requirements of § 1910.1028 except as specifically exempted by § 1910.1028(a)(2). Exposures exempted by § 1910.1028(a)(2) are covered by this § 1910.1000

(ii) The storage, transportation, distribution or sale of benzene in intact containers sealed in such a manner as to contain benzene vapors or liquid, except for the requirements of paragraph (k) (2), (3), (4), and (5), and paragraph (j) of this section.

(b) *Definitions.* "Action level" means an airborne concentration of benzene of 0.5 ppm, averaged over an 8-hour work day.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person required by his duties to enter a regulated area and authorized to do so by his employer, by this section or by the Occupational Safety and Health Act of 1970. "Authorized person" includes a representative of employees who is designated to observe monitoring and measuring procedures under paragraph (m) of this section.

"Benzene" (C_6H_6) (CAS Registry No. 00071432) means solid, liquefied or gaseous benzene. It includes mixtures of liquids containing benzene and the vapors released by these liquids.

"Bulk terminal" means a facility which is used for the storage and distribution of gasoline, motor fuels or other fuels and which receives its petroleum products by pipeline, barge or marine tanker.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may, or does, result in a massive release of benzene.

"OSHA Area Office" means the office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits*—(1) *Inhalation*—(i) *Time-weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average.

(ii) *Ceiling limit.* The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of 5 ppm as averaged over any 15 minute period.

(2) *Dermal and eye exposure limit.* The employer shall assure that no employee is exposed to eye contact with liquid benzene; or to skin contact with liquid benzene, unless the employer can establish that the skin contact is an isolated instance.

(d) *Regulated areas.* (1) the employer shall establish, within each place of employment, regulated areas where benzene concentrations are in excess of the permissible airborne exposure limit.

(2) The employer shall limit access to regulated areas to authorized persons.

(3) *Notification of regulated areas.* Within 30 days following the establishment of a regulated area, the employer shall report the following information to the OSHA Area Office:

(i) The address of each establishment which has one or more regulated areas;

(ii) The locations, within the establishment, of each regulated area;

(iii) A brief description of each process or operation which results in employee exposure to benzene in regulated areas; and

(iv) The number of employees engaged in each process or operation within each regulated area which results in exposure to benzene, and an estimate of the frequency and degree of exposure within each regulated area.

(e) *Exposure monitoring and measurements.*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to benzene over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which could occur if the employee were not using a respirator.

(2) *Initial monitoring.* (i) Each employer, who has a place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used shall monitor each of these workplaces and work operations to accurately determine the airborne concentrations of benzene to which employees may be exposed.

(ii) The initial monitoring required under paragraph (e)(2)(i) of this section shall be conducted and the results obtained within 30 days of the effective date of this section. Where the employer has monitored after January 4, 1977 and the monitoring satisfies the accuracy requirements of paragraph (e)(6) of the section, the employer may rely on such earlier monitoring to satisfy the requirements of paragraph (e)(2)(i) of this section, unless there has been a production, process, personnel or control change which may have resulted in new or additional exposures to benzene or the employer has any other reason to suspect a change which may have resulted in new or additional exposures to benzene; and provided that the employer maintains a record of the monitoring in accordance with paragraph (l)(1) and notifies each employee in accordance with paragraph (e)(5).

(3) *Frequency.*—(i) *Measurements below the action level.* If the measurements conducted under paragraph (e)(2)(i) of this section reveal employee exposure to be below the action level, the measurements need not be repeated, except as otherwise provided in paragraph (e)(4) of this section.

(ii) *Measurements above the action level.* If the measurements reveal employee exposure to be in excess of the action level, but below the permissible exposure limit, the employer shall repeat the monitoring at least quarterly. The employer shall continue these quarterly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the action level, and thereafter the employer may discontinue monitoring, except as provided in paragraph (e)(4) of this section.

(iii) *Measurements above the permissible exposure limit.* If the measurements reveal employee exposure to be in excess of the permissible exposure limits, the employer shall repeat the measurements at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, personnel or control change which may result in new or additional exposure to benzene or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to benzene, such as spills, leaks, ruptures, or breakdowns, the employer shall repeat the monitoring which is required by paragraph (e)(2)(i) of this section.

(5) *Employee notification.* (i) Within 5 working days after the receipt of the measurement results, the employer shall notify each employee in writing of the exposure measurements which represent that employee's exposures.

(ii) Where the results indicate that the employee's exposure exceeds the permissible exposure limits, the notification shall also include the corrective action being taken or to be taken by the employer to reduce exposure to or below the permissible exposure limit.

(6) *Accuracy of measurement.* The employer shall use a method of measurement which has an accuracy, to a confidence level of 95 percent, of not less than plus or minus 25 percent for concentrations of benzene greater than or equal to 1 ppm.

(f) *Methods of compliance.*—(1) *Priority of compliance methods.* The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to benzene at or below the permissible exposure limits, except to the extent that the employer establishes that these controls are not feasible. Where feasi-

ble engineering and work practice controls are not sufficient to reduce employee exposure to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls, and shall supplement them by the use of respiratory protection.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls required by paragraph (f)(1) of this section.

(ii) The written program shall include a schedule for development and implementation of the engineering and work practice controls. These plans shall be revised at least every six months to reflect the current status of the program.

(iii) Written plans for these compliance programs shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and the employees or their authorized representatives.

(iv) The employer shall institute and maintain at least the controls described in his most recent written compliance program.

(g) *Respiratory protection.*—(1) *General.* Where respiratory protection is required under this section, the employer shall select, provide and assure the use of respirators. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement feasible engineering and work practice controls;

(ii) During maintenance and repair activities in which engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health under the program of 30 CFR Part 11.

(3) *Respirator program.* The employer shall institute a respiratory protection program in a accordance with § 1910.134(b), (d), (e) and (f).

(4) *Respirator use.* (i) Where air purifying respirators (cartridge, canister, or gas mask) are used, the employer shall, except as provided in paragraph (g)(4)(ii) of this section, replace the air-purifying canisters or cartridges prior to the expiration of their service life or the end of shift in which they are first used, whichever occurs first.

(ii) Where a cartridge or canister of an air purifying respirator has an end of service life indicator certified by NIOSH for benzene, the employer may permit its use until such time as the indicator shows the end of service life.

(iii) The employer shall assure that the respirator issued to the employee exhibits minimum facepiece leakage and that the respirator is properly fitted

(iv) The employer shall allow each employee who wears a respirator to wash his or her face and respirator facepiece to prevent skin irritation association with respirator use.

TABLE I.—*Respiratory protection for benzene*

Airborne concentration of benezene or condition of use	*Respirator type*
(a) Less than or equal to 10 p/m.	(1) Any chemical cartridge respirator with organic vapor cartridge; or (2) Any supplied air respirator.
(b) Less than or equal to 50 p/m.	(1) Any chemical cartridge respirator with organic vapor cartridge and full facepiece; (2) Any supplied air respirator with full facepiece; (3) Any organic vapor gas mask; or (4) Any self-contained breathing apparatus with full facepiece.
(c) Less than or equal to 1,000 p/m.	(1) Supplied air respirator with half mask in positive pressure mode.
(d) Less than or equal to 2,000 p/m.	() Supplied air respirator with full facepiece, helmet, or hood, in positive pressure mode.
(e) Less than or equal to 10,000 p/m.	(1) Supplied air respirator and auxiliary self-contained facepiece in positive pressure mode; or (2) Open circuit self-contained breathing apparatus with full facepiece in positive pressure mode.
(f) Escape	(1) Any organic vapor gas mask; or (2) Any self-contained breathing apparatus with full facepiece.

(h) *Protective clothing and equipment.* Where eye or dermal exposure may occur, the employer shall provide, at no cost to the employee, and assure that the employee wears impermeable protective clothing and equipment to protect the area of the body which may come in contact with liquid benzene. Eye and face protection shall meet the requirements of § 1910.133 of this Part.

(i) *Medical Surveillance*—(1) *General.* (i) The employer shall make available a medical surveillance program for employees who are or may be exposed to benzene at or above the action level and employees who are subjected to an emergency.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and provided without cost to the employee.

(2) *Initial examinations.* (i) Within thirty days of the effective date of this section, or before the time of initial assignment, the employer shall provide each employee who is or may be exposed to benzene at or above the action level with a medical examination, including at least the following elements:

(*a*) A history which includes past work exposure to benzene or any other hematologic toxins; a family history of blood dyscrasias including hematological neoplasms; a history of blood dyscrasias including genetically related hemoglobin alterations, bleeding abnormalities, abnormal function of formed blood elements; a history of renal or liver dysfunction; a history of drugs routinely taken, alcoholic intake and systemic infections; a history of exposure to marrow toxins outside of the current work situation, including volatile cleaning agents and insecticides;

(*b*) Laboratory tests, including a complete blood count with red cell count, white cell count with differential, platelet count, hematocrit, hemoglobin and red cell indices (MCV, MCH, MCHC), serum bilirubin and reticulocyte count; and

(*c*) Additional tests where, in the opinion of the examining physician, alterations in the components of the blood are related to benzene exposure.

(ii) No medical examination is required to satisfy the requirements of paragraph (i)(2)(i) of this section if adequate records show that the employee has been examined in accordance with the procedures of paragraph (i)(2)(i) of this section within the previous six months.

(3) *Information provided to the physician.* The employer shall provide the following information to the examining physician for each examination under this section:

(i) A copy of this regulation and its appendixes;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physican.

(4) *Physician's written opinions.* (i) For each examination under this section, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion containing the following:

(*a*) The results of the medical examination and tests;

(*b*) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to benzene;

(*c*) The physician's recommended limitations upon the employee's exposure to benzene or upon the employee's use of protective clothing or equipment and respirators.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(5) *Periodic examinations* (i) The employer shall provide each employee covered under paragraph (i)(1)(i) of this section with a medical examination at least semi-annually following the initial examination. These periodic examinations shall include at least the following elements:

(*a*) A brief history regarding any new exposure to potential marrow toxins, changes in drug and alcohol intake and the appearance of physical symptoms relating to blood disorders;

(*b*) A complete blood count with red cell count, white cell count with differential, platelet count, hemoglobin, hematocrit and red cell indices (MCV, MCH, MCHC); and

(*c*) Additional tests where in the opinion of the examining physician, alterations in the components of the blood are related to benzene exposure.

(ii) Where the employee develops signs and symptoms commonly associated with toxic exposure to benzene, the employer shall provide the employee with a medical examination which shall include those elements considered appropriate by the examining physician.

(6) *Emergency situations.* If the employee is exposed to benzene in an emergency situation, the employer shall provide the employee with a urinary phenol test at the end of the employee's shift. The urine specific gravity shall be corrected to 1.024. If the result of the urinary phenol test is below 75 mg/ml, no further testing is required. If the result of the urinary phenol test is equal to or greater than 75 mg/ml, the employer shall provide the employee with a complete blood count including a red cell count, white cell count with differential, and platelet count as soon as practicable, and shall provide these same counts one month later.

(7) *Special examinations.* (i) Where the results of any tests required by this section reveal that any of the following conditions exist, the employer shall have the test results of the employee evaluated by a hematologist:

(*a*) The red cell count, hemoglobin or platelet count varies more than 15 percent above or below the employee's most recent values;

(*b*) The red cell count is below 4.4 million or above 6.3 million per mm^3, (for males), or below 4.2 million or above 5.5 million per mm^3 (for females);

(*c*) The hemoglobin is below 14 grams percent or above 18 grams percent (for males) or below 12 grams percent or above 16 grams percent (for females);

(*d*) The white cell count is below 4,200 or above 10,000;

(*e*) The thrombocyte count is below 140×10^3 cells per mm^3 or above 440×10^3 cells per mm^3.

(ii) In addition to the information required to be provided to the physician under paragraph (i)(3) of this section, the employer shall provide the hematologist with the medical record required to be maintained by paragraph (l)(2) of this section.

(iii) The hematologist's evaluation shall include a determination as to the need for additional tests, and the employer shall assure that these tests are provided.

(j) *Employee information and training*—(1) *Training program.* (i) The employer shall institute a training program for all employees assigned to workplaces where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used and shall assure that each employee assigned to these workplaces is informed of the following:

(*a*) The information contained in Appendices A and B of this section;

(*b*) The quantity, location, manner of use, release, or storage of benzene and the specific nature of operations which could result in exposure above the permissible exposure limits as well as necessary protective steps;

(*c*) The purpose, proper use, and limitations of personal protective equipment and clothing required by paragraph (h) of this section and of respiratory devices required by paragraph (g) of this section and § 1910.134 (b), (d), (e) and (f);

(*d*) The purpose and a description of the medical surveillance program required by paragraph (i) of this section and the information contained in Appendix C of this section; and

(*e*) The contents of this standard.

(ii) The training program required under paragraph (j)(1)(i) of this section shall be provided within 90 days of the effective date of this section or at the time of initial assignment to workplaces where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled or used, and at least annually thereafter.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its Appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(k) *Signs and labels.* (1) The employer shall post signs in regulated areas bearing the following legend:

DANGER

BENZENE

CANCER HAZARD

FLAMMABLE—NO SMOKING

AUTHORIZED PERSONNEL ONLY

RESPIRATOR REQUIRED

(2) The employer shall assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene, except:

(i) Pipelines, and

(ii) Transport vessels or vehicles carrying benzene or benzene products in sealed intact containers.

(3) The employer shall assure that the caution labels remain affixed when the benzene or products containing benzene are sold, distributed or otherwise leave the employer's workplace.

(4) The caution labels required by paragraph (k)(2) of this section shall be readily visible and legible. The labels shall bear the following legend:

CAUTION

CONTAINS BENZENE

CANCER HAZARD

(5) The employer shall assure that no statement which contradicts or detracts from the information required by paragraphs (k)(1) and (k)(4) of this section appears on or near any required sign or label.

(l) *Recordkeeping.*—(1) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (e) of this section.

(ii) This record shall include:

(*a*) The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

(*b*) A description of the sampling and analytical methods used;

(*c*) Type of respiratory protective devices worn, if any; and

(*d*) Name, social security number, and job classification of the employee monitored and all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the

duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (i) of this section.

(ii) This record shall include:

(*a*) The name, and social security number of the employee;

(*b*) A copy of the physicians' written opinions, including results of medical examinations and all tests, opinions and recommendations;

(*c*) The peripheral blood smear slides of the initial test, the most recent test, and any test demonstrating hematological abnormalities related to benzene exposure;

(*d*) Any employee medical complaints related to exposure to benzene;

(*e*) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and its appendices for all employees provided that he references the standard and its appendices in the medical surveillance record of each employee;

(*f*) A copy of the information provided to the physician as required by paragraphs (i)(3)(ii) through (i)(3)(v) of this section; and

(*g*) A copy of the employee's medical and work history related to exposure to benzene or any other hematologic toxins.

(iii) The employer shall maintain this record for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records as required by this section be made available for examination and copying to affected employees or their designated representatives.

(iii) The employer shall assure that former employees and the former employees' designated representatives have access to such records as will indicate the former employee's own exposure to benzene.

(iv) The employer shall assure that employee medical records required to be maintained by this section be made available upon request for examination and copying to a physician or other individual designated by the affected employee or former employee.

(4) *Transfer of records.* (i) When the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (l) of this section for the prescribed period.

(ii) When the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall transmit these records by mail to the Director.

(iii) At the expiration of the retention period for the records required to be maintained under paragraph (l) of this section, the employer shall transmit these records by mail to the Director.

(m) *Observation of monitoring.*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any measuring or monitoring of employee exposure to benzene conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) When observation of the measuring or monitoring of employee exposure to benzene requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the measurement, observers shall be entitled to:

(*a*) Receive an explanation of the measurement procedures;

(*b*) Observe all steps related to the measurement of airborne concentrations of benzene performed at the place of exposure; and

(*c*) Record the results obtained.

(n) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligations.

Appendix A—Substance Safety Data Sheet, Benzene

I. Substance Identification

A. *Substance.* Benzene.

B. *Permissible Exposure:* Except as to the use as fuels of gasoline, motor fuels and other fuels subsequent to discharge from bulk terminals.

1. *Airborne.* 1 part of benzene vapor per million parts of air (1 ppm); time-weighted average (TWA) for an 8-hour workday for a 40-hour week, with a 15 minute ceiling concentration of 5 ppm.

2. *Dermal.* Eye contact and skin contact with liquid benzene shall be prohibited.

C. *Appearance and odor.* Benzene is a clear, colorless liquid with a pleasant, sweet odor. The odor of benzene does not provide adequate warning of its hazard.

II. Health Hazard Data

A. *Ways in which the benzene affects your health.* Benzene can affect your health if you inhale it, or if it comes in contact with your skin or eyes. Benzene is also harmful if you happen to swallow it.

B. *Effects of overexposure.* 1. Short-term (acute) overexposure: If you are overexposed to high concentrations of benzene, well above the levels where its odors are first recognizable, you may feel breathless, irritable, euphoric, or giddy; you may experience irritation in eyes, nose, and respiratory tract. You may develop a headache, feel dizzy, nauseous, or experience unsteadiness in walking. Severe exposures may lead to convulsions.

2. *Long-term (chronic) exposure.* Repeated or prolonged exposure to benzene, even at relatively low concentrations, may result in various blood disorders, ranging from anemia to leukemia, an irreversible, fatal disease. Many blood disorders associated with benzene exposure may occur without physical symptoms.

III. Protective Clothing and Equipment

A. *Respirators.* Respirators are required for those operations in which engineering controls or work practice controls are not feasible to reduce exposure to the permissible level. If respirators are worn, they must have a National Institute for Occupational Safety and Health (NIOSH) seal of approval, and cartridges or canisters must be replaced before the end of their service life, or the end of the shift, whichever occurs first. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. *Protective Clothing.* You must wear impervious protective clothing (such as boots, gloves, sleeves, aprons, etc.) over any parts of your body that could be exposed to liquid benzene.

C. *Eye and Face Protection.* You must wear splash proof safety goggles if it is possible that benzene may get into your eyes. In addition, you must wear a face shield if your face could be splashed with benzene liquid.

IV. Emergency and First Aid Procedures

A. *Eye and face exposure.* If benzene is splashed in your eyes, wash it out immediately with large amounts of water. Call a doctor as soon as possible.

B. *Skin exposure.* If benzene is spilled on your clothing or skin, remove the contaminated clothing and wash the exposed skin with large amounts of water and soap immediately. Wash contaminated clothing before you wear it again.

C. *Breathing.* If you or any other person breathes in large amounts of benzene, get the exposed person to fresh air at once. Apply artificial respiration if breathing has stopped. Call for medical assistance or a doctor as soon as possible.

D. *Swallowing.* If benzene has been swallowed and the patient is conscious, do not induce vomiting. Call for medical assistance or a doctor immediately.

V. Medical Requirements

If you are exposed to benzene at a concentration at or above 0.5 ppm on an 8-hour time-weighted average, your employer is required to provide a medical history and laboratory tests within 30 days of the effective date of this standard and semiannually thereafter if you are continually exposed at or above 0.5 ppm. These tests shall be provided without cost to you. In addition, if you are accidentally exposed to benzene (either by ingestion, inhalation, or skin/eye contact) under conditions known or suspected to be toxic exposure to benzene, your employer is required to make special tests available to you.

VI. OBSERVATION OF MONITORING

Your employer is required to perform measurements that are representative of your exposure to benzene and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to receive an explanation of the measurement procedure, observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

VII. ACCESS TO RECORDS

You or your representative are entitled to see the records of measurements of your exposure to benzene upon request to your employer. Your medical examination records can be furnished to your physician or designated representative upon request to your employer.

VIII. PRECAUTIONS FOR SAFE USE, HANDLING AND STORAGE

Benzene liquid is highly flammable. It should be stored in tightly closed containers in a cool, well ventilated area. Benzene vapor may form explosive mixtures in air. All sources of ignition must be controlled. Use nonsparking tools when opening or closing benzene containers. Ground or bond metal benzene containers. Fire extinguishers, where provided, must be readily available. Know where they are located and how to operate them. Smoking is prohibited in areas where benzene is used or stored. Ask your supervisor where benzene is used in your work area and for additional plant safety rules.

APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES, BENZENE

I. PHYSICAL AND CHEMICAL DATA

A. *Substance identification.*

1. Synonyms: Benzol, benzole, coal naptha, cyclohexatriene, phene, phenyl hydride, pyrobenzol. (Benzine, petroleum benzine, and benzine do not contain benzene.)

2. Formula: C_6H_6 (CAS Registry Number: 000071432)

B. *Physical data.*

1. Boiling Point (760 mm Hg): 80.1C (176F)

2. Specific Gravity (water = 1): 0.879

3. Vapor Density (air = 1): 2.7

4. Melting Point: 5.5C (42F)

5. Vapor Pressure at 20 C (68F): 75 mm Hg

6. Solubility in Water: .06%

7. Evaporation Rate (ether = 1): 2.8

8. Appearance and Odor: Clear, colorless liquid with a distinctive sweet odor.

II. FIRE, EXPLOSION, AND REACTIVITY HAZARD DATA

A. *Fire.*

1. Flash Point (closed cup): -11 C (12F)

2. Autoignition Temperature: 580 C (1076F)

3. Flammable Limits in Air, % by Volume: Lower 1.3%, Upper: 7.5%

4. Extinguishing Media: Carbon dioxide, dry chemical, or foam.

5. Special Fire-Fighting Procedures: Do not use solid stream of water, since stream will scatter and spread fire. Water spray can be used to keep fire exposed containers cool.

6. Unusual fire and explosion hazards: Benzene is a flammable liquid. Its vapors can form explosive mixtures. All ignition sources must be controlled when benzene is used, handled, or stored. Where liquid or vapor may be released, such areas shall be considered as hazardous locations. Benzene vapors are heavier than air; thus the vapors may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which benzene is handled.

7. Benzene is classified as a *1 B flammable liquid* for the purpose of conforming to the requirements of 29 CFR 1910.106. A concentration exceeding *3250 ppm* is considered a potential fire explosion hazard. Locations where benzene may be present in quantities sufficient to produce explosive or ignitable mixtures are considered *Class I Group D* for the purposes of conforming to the requirement of 29 CFR 1910.309.

B. *Reactivity.*

1. Conditions contributing to instability: Heat.

2. Incompatibility: Heat and oxidizing materials.

3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide).

III. SPILL AND LEAK PROCEDURES

A. *Steps to be taken if the material is released or spilled.* As much benzene as possible should be absorbed with suitable materials, such as dry sand or earth. That remaining must be flushed with large amounts of water. Do not flush benzene into a confined space, such as a sewer, because of explosion danger. Remove all ignition sources. Ventilate enclosed places.

B. *Waste disposal method.* Disposal methods must conform to other jurisdictional regulations. If allowed, benzene may be disposed of: (a) Absorbing it in dry sand or earth and disposing in a sanitary land fill; (b) if small quantities, by removing it to a safe location from buildings or other combustible sources, pouring it in dry sand or earth and cautiously igniting it; (c) if large quantities, by atomizing it in a suitable combustion chamber.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. *Normal monitoring program.* Measurements taken from the purpose of determining employee exposure are best taken so that the representative average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Short-time interval samples (or grab samples) may also be used to determine average exposure level if a minimum of five measurements are taken in a random manner over the 8-hour work shift. Random sampling means that any portion of the work shift has the same chance of being sampled as any other. The arithmetic average of all such random samples taken on one work shift is an estimate of an employee's average level of exposure for that work shift. Air samples should be taken in the employee's breathing zone (air that would nearly represent that inhaled by the employee). Sampling must be performed by gas adsorption tubes or alternative methods meeting the requirements of the standard with subsequent chemical analysis, by gas chromatography. Methods meeting the prescribed accuracy and precision and requirements are available in the "NIOSH manual of Analytical Methods."

V. MISCELLANEOUS PRECAUTIONS

A. High exposures to benzene can occur when transferring the liquid from one container to another. Such operations should be well ventilated and good work practices must be established to avoid spills.

B. Use non-sparking tools to open benzene containers which are effectively grounded and bonded prior to opening and pouring.

C. Employers must advise employees of all plant areas and operations where exposure to benzene could occur. Common operations in which high exposures to benzene may be encountered are: the primary production and utilization of benzene, and transfer of benzene.

APPENDIX C—MEDICAL SURVEILLANCE GUIDELINES FOR BENZENE

I. ROUTE OF ENTRY

Inhalation; possible skin absorption.

II. TOXICOLOGY

Benzene is primarily an inhalation hazard. Systemic absorption may cause depression of the hematopoietic system and leukemia. Inhalation of high concentrations can affect the central nervous system function. Aspiration of small amounts of liquid benzene immediately causes pulmonary edema and hemorrhage of pulmonary tissue. The extent of absorption through the skin is unknown. However, absorption may be accelerated in the case of injured skin, and benzene may be more readily absorbed if it is present in a mixture or as a contaminant in solvents which are readily absorbed. Defatting action of benzene may produce primary irritation upon repeated or prolonged contact with the skin. High concentrations are irritating to the mucuous membranes of the eyes, nose, and respiratory tract.

III. SIGNS AND SYMPTOMS

It is not clear to what extent benzene is absorbed through the skin, however, direct contact may cause erythema or blistering. Repeated or prolonged contact may result in drying, scaling dermatitis, or precipitate development of secondary skin infections. Local effects of benzene vapor or liquid on the eye are slight. Only at very high concentrations is there any smarting sensation in the eye. Inhalation of high concentrations of benzene may have an initial stimulatory effect on the central nervous system characterized by exhiliration, nervous excitation, and/or giddiness, followed by a period of depression, drowsiness, fatigue, or vertigo. There may be sensation of tightness in the chest accompanied by breathlessness and ultimately the victim may lose consciousness. Convulsions and tremors occur frequently, and death may follow from respiratory paralysis or circulatory collapse in a few minutes to several hours following severe exposures.

The insidious effect on the blood-forming system of prolonged exposure to small quantities of benzene vapor is of extreme importance. The hematopoietic system is the chief target for benzene's toxic effects which are manifested by alterations in the levels of formed elements in the peripheral blood. These effects have been noted to occur at concentrations of benzene which may not cause irritation of mucous membranes, or any unpleasant sensory effects. Early signs and symptoms of benzene morbidity are varied and often not overtly apparent and not specific for benzene exposure. Subjective complaints of headache,

dizziness, and loss of appetite may precede or follow clinical symptomology. Bleeding from the nose, gums, or mucous membranes and the development of purpuric spots may occur as the condition progresses. Rapid pulse and low blood pressure in addition to a physical appearance of anemia may accompany a subjective complaint of shortness of breath. Clinical evidence of leukopenia, anemia, and thrombocytopenia, singly or in combination, have been frequently reported.

Bone marrow may appear normal, aplastic, or hyperplastic and may not in all situations correlate with peripheral blood forming tissues. There are great variations in the susceptibility to benzene morbidity which prohibits the identification of "typical" blood picture.' The onset of effects of prolonged benzene exposure may be significantly delayed after the actual exposure has ceased.

IV. TREATMENT OF ACUTE TOXIC EFFECTS

Remove from exposure immediately, give oxygen or artificial resuscitation if indicated. Flush eyes and wash contaminated skin. Symptoms of non-specific nervous disturbances may persist following severe exposures. Recovery from mild exposures is usually rapid and complete.

V. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. GENERAL

The principal effects of benzene exposure forming the basis for this regulation are alterations of the hematopoietic system as reflected by changes in the peripheral blood and leukemia. Consequently, the medical surveillance protocol is designed to observe on a regular basis, blood indices for early signs of these effects.

Tests must be performed frequently enough to discover individuals who may be unusually sensitive and likely to develop marrow abnormalities, to monitor those who experience accidental overexposure and to provide early detection of delayed evidence of toxicity.

All workers who are or will be exposed to 0.5 parts per million (ppm) or greater benzene as an eight-hour time-weighted average are to be given the opportunity for a medical examination. Initial examinations are to be provided within 30 days of the effective date of this standard or at the time of initial assignment and interval examinations semiannually thereafter. There are special provisions for medical tests in the event of hematolgica abnormalities or for emergency situations.

F. HEMATOLOGY GUIDELINES

The following information excerpted from the analysis of Dr. Jandl, Chief of Hematology, Harvard School of Medicine, may be useful to physicians in conducting the medical surveillance program.

"A minimum battery of tests is to be performed by strictly standardized methods in the circumstances described above.

1. Red cell, white cell, and platelet counts must be performed using an automated (Coulter) counter. The normal range for the red cell count is approximately 4.4 to 6.0 million cells/mm³, the values for women being about 0.4 million cells lower than for men. A decline from a normal to a subnormal value, or a rise to a supra-normal value, are indicative of potential toxicity, particularly should there be a decline. The normal total white blood count is approximately 6,200 plus or minus 2,000/mm³. For cigarette smokers and white count will be higher, the upper range of "normal" being approximately 1,000 cells higher than 8,200. Either a decline from normal to subnormal or a rise from normal to supra-normal, should be regarded as a potential indication of benzene toxicity. The normal platelet count is 250,000 with a range of 140,000 to (at most) 400,000/mm³. A decline to below 140,000 or a rise to above 400,000 should be regarded as possible evidence of benzene toxicity.

The reticulocyte count is performed by technical assistants using a cover-slip smear (see below). In my opinion, the preferred technique for this purpose is the so-called "dry-method" employing brilliant cresyl blue (BCB) for staining the filaments of reticulum within red cell, and counter-staining with Wright's stain. The extreme range of normal for reticulocytes is 0.4 to 1.5 percent of the red cells, the usual range being 0.5 to 1.2 percent of the red cells, but the typical value is in the range of 0.8 to 1.0 percent. There is an advantage of using the BCB reticulocyte staining technique (followed by counter-staining with Wright's stain) in that visible evidence (i.e., the stained, mounted reticulocyte smears) may be stored, and if kept filed in the dark may later be retrieved for reexamination and comparisons. A decline in reticulocytes to levels of less than 0.4 percent is to be regarded as possible evidence (unless another specific cause is found) of benzene toxicity requiring accelerated surveillance. An increase in reticulocyte levels to above 1.5 percent may also be consistent with (but is not as characteristic of) benzene toxicity.

2. The single most important routine surveillance test is an expert technician's careful examination of the peripheral blood smear. As with the reticulocyte count, the smear should be with fresh uncoagulated blood obtained from a needle tip following venipuncture or from a drop of earlobe blood (capillary blood). If necessary, the smear may under certain limited conditions be made from a blood sample anticoagulated with EDTA (but never with oxalate or heparin). When the smear is to be prepared from a specimen of venous blood which has been collected by a commercial Vacutainer® type tube containing neutral EDTA, the smear should be made as soon as possible after the venesection. A delay of up to 12 hours is permissible between the drawing of the blood specimen into EDTA and the preparation of the smear if the blood is stored at refrigerator (not freezing) temperature. As with the reticulocyte preparations, the smear should be made on cover slips only. Under no circumstances should peripheral blood (or bone marrow aspirate) intended for examination be smeared on microscope slides, a technique which produces artifacts in blood cells and distorts the white cell differential count by severely maldistributing them. Dry blood smears should be stained with Wright's stain which should be filtered at least weekly to remove precipated dye (saturated completely by methylene blue-eosinate derivates).

3. The minimum mandatory observations to be made from the smear and a discussion of their significance now follows. The observations are four:

a. The differential white blood cell count.

b. Description of abnormalities in the appearance of red cells.

c. Description of any abnormalities in the platelets.

d. A careful search must be made by the technician throughout the better areas of every blood smear for immature white cells such as band forms (in more than normal proportion), any number of metamyelocytes, myelocytes. Any nucleated or multinucleated red blood cells should be reported. Very large "giant" platelets of fragments of megakaryocytes must be recognized. Should only a single one of these abnormalities be found, it should be reported.

An increase in the proportion of band forms among the neutrophilic granulocytes is an abnormality deserving special mention for it represents a very early change which should be considered as an early warning of benzene toxicity in the absence of other causative factors (most commonly infection). Likewise, the appearance of metamyelocytes in the absence of other probable cause is to be considered a possible indication of benzene-induced injury.

An upward trend in the number of basophils, which normally do not exceed about 2.0 percent of the total white cells, is to be regarded as possible evidence of benzene toxicity. A rise in the eosinophil count is less specific but also may be suspicious of toxicity if it rises above 6.0 percent of the total white count.

The normal range of monocytes is from 2.0 to 8.0 percent of the total white count an average of about 5.0 percent. About 20 percent of individuals reported to have mild but persisting abnormalities caused by exposure to benzene show a persisting monocytosis which is sometimes striking. The findings of a monocyte count which persists at more than 10 to 12 percent of the normal white cell count (when the total count is normal) or persistance of an absolute monocyte count in excess 800/mm³ should be regarded as a possible sign of benzene-induced injury.

A less frequent but more serious indication of benzene-induced injury to the bone marrow is the findings in the peripheral blood of the so-called "pseudo" (or acquired) Pelger-Huet anomaly. In this anomaly many, or sometimes the majority, of the neutrophilic granulocytes possess two round nuclear segments—less often one or three round segments—rather than three normally elongated segments. When this anomaly is not hereditary, it is often but not invariably predictive of subsequent leukemia. However, only about two percent of patients who ultimatly develop acute myelogenous leukemia show the acquired Pelger-Huet anomaly.

An uncommon but ominous sign, one which cannot be detected from the smear, but can be suspected easily by a "sucrose water test" or peripheral blood, is transient paroxysmal nocturnalhemoglobinuria (PNH), which may first occur insidiously during a period of established aplastic anemia and maybe followed within one to a few years by the appearance of rapidly fatal acute myelogenous leukemia. Clinical detection of PHH, which occurs in perhaps only one or two percent of those destined to have acute myelogenous leukemia, may be duffficult; if the presumptive "sucrose water test" for it is positive, the technician may perform the somewhat more definitive Ham test, also known as the acid-serum hemolysis test.

e. Individuals documented to have developed acute myelogenous leukemia years after initial exposure to benzene, have (see above) progressed through preliminary phases of hematologic abnormality. In

many instances pancytopenia (i.e., a lowering in the counts of all circulating blood cells of bone marrow orgin—but not to the extent implied by the term "aplastic anemia") preceded leukemia for many years. Seldom does relative scarcity of a single type blood cell (or of platelets) represent a harbinger of imminent acute leukemia. However, the finding of two or more cytopenias, or of pancytopenia, must be regarded as highly suspicious of more advance although still reversible, benzene toxicity. When "pancytopenia" develops and becomes associated with the appearance of immature cells (myelocytes, myeloblasts, erythroblasts, etc.), with abnormal cells (pseudo Pelger-Huet anomaly, atypical nuclear heterochromatin, etc.), or with inappropriate elevations of monocytes, basophils, or eosinsophils, the findings must be regarded as evidence of benzene overexposure unless proved other-wise. These and other aggregates of alterations are frequently term "preleukemia," a term whose meaning is good when used retrospectively, but less good when used prospectively where it has only inferential value. Many severely aplastic patients manifested the ominious finding of 5–10 percent myeloblasts in the marrow, occasional myeloblasts and myelocytes in the blood and 20–30% monocytes; these represented the beginning of recovery rather than the early stage of overt AML. Thus, a considerable proportion of "preleukemias" in benzene poisioning fail to progress to leukemia. Indeed, some have been observed to revert to normal after withdrawal of the afflicted person from toxic exposure. Nonetheless, the chance that "preleukemic" (changes in general) will evolve to leukemia is considerable: at least 20 to 40 percent of persons (only a few of whom were benzene-exposed) with these blood changes develop acute myelogenous leukemia. Certain tests may substantiate the person's prospects for progression or regression. One such test would be an examination of patient's bone marrow. But the decision to perform a bone marrow aspiration or needle biobsy is one that should be made by the hematologist. The findings to be sought there would be: hypoplasia or aplasia; an excess of immature forms; vacuolation in erythroblasts and myelocytes—a phenomenon induced by many toxins apart from benzene, including chloramphenicol and alcohol; and by infections.

The findings of basophilic stippling in circulating red blood cells (usually found in 1 to 5% of red cell during marrow injury), and detection in the bone marrow of what are termed "ringed sideroblasts" must be taken seriously, as they have been noted in recent years to be frequent premonitory signs of subsequent acute leukemia.

In several recent reports dealing with relatively few patients, peroxidase-staining of circulating or marrow neutrophil granules, employing benzidine dihydrochloride, has revealed as a "preleukemic" finding the disappearance of, or diminution in, perosidase in a sizable proportion of the granulocytes. Granulocyte granules are normally strongly peroxidase positive. A steady decline in leukocyte alkaline phosphatase is also suggestive of early acute leukemia. Exposure to benzene commonly causes an early rise in serum iron, often but not always associated with a fall in the reticulocyte count. Thus serial measurements of serum iron levels provide a means of determining whether or not there is a trend representing sustained suppress of erythropoiesis.

Measurement of serum iron, determination of peroxidase and of alkaline phosphatase activity in peripheral granulocytes can be performed by technical assistants.

(Secs. 4, 6, 8, 84 Stat. 1593, (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR part 1911.)

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